3.0 Conducting the Tier 2 BERA

3.1 Introduction

On the basis of the outcome of the Tier 1 SRA, the RPM has made one of three possible decisions (Figure 3.1). If the Tier 1 results identified no complete pathways or unacceptable risks to ecological resources, then the decision would be to close out the site with regards to ecological concerns. Alternately, if the Tier 1 SRA identified immediate and unacceptable risks to ecological resources or unacceptable risks that could be quickly addressed in a cost-effective manner, then the decision would be to initiate interim cleanup. Lastly, if the Tier 1 SRA identified a number of contaminants that may pose unacceptable risks to ecological resources, then the decision would be to proceed to a Tier 2 Baseline Ecological Risk Assessment (BERA).

The Tier 2 BERA consists of a number of steps (Figure 3.1) designed to provide a scientifically based and defensible assessment of exposure and hazard to ecological resources that will support a risk management decision regarding site cleanup. These steps include a reevaluation of the Tier 1 results using less conservative assumptions, problem formulation, development of a study design and data quality objectives, data collection and analysis, and risk characterization. Upon the completion of these steps, the RPM will have sufficient information to assist in making one of two risk management decisions for the site under evaluation: remediation from an ecological perspective is not warranted, or the site should proceed to Tier 3 for remedy development and evaluation.

This portion of the web site provides guidance for designing and managing the Tier 2 BERA in accordance with the CNO ERA Policy and consistent with the current Superfund ERA guidance.

3.1.1 Overseeing the Tier 2 BERA

As the RPM, you are responsible for keeping your site moving forward through the ER process, doing so within the approved budget and schedule, and ensuring that a defensible and appropriate Tier 2 BERA is produced to support your ultimate risk management decision. As part of this process, it is your responsibility to maintain control and involvement over the risk assessment team and the risk assessment process. To effectively meet this responsibility, you should work closely with your risk assessor to make sure that you understand the rationale and uncertainties associated with all the aspects of the Tier 2 evaluation. This understanding should include, but not be limited to:

- Problem Formulation;
- Study Design and Data Quality Objectives (DQOs);
- Risk Characterization;
- Determination of Ecological Significance;

- Risk Acceptability; and
- Uncertainty Evaluations.

One way to develop such an understanding is for the RPM to hold regular coordination and status meetings with their risk assessment team and site characterization staff. During these meetings, do not hesitate to ask questions about assumptions related to problem formulation and the conceptual site model, data collection and evaluation methods, sampling plans, etc., and do not proceed with any proposed activities until you have attained an acceptable level of familiarity and comfort with those activities. Remember, if you do not understand a particular activity, assumption, or evaluation, you will not be able to adequately address regulator and/or public comments or concerns on those matters.

3.1.2 Team Identification

In contrast to the Tier 1 SRA, for which a large technical staff should not be required, technical staffing for the Tier 2 BERA will typically require a diverse technical risk assessment staff. Depending on the nature of the site and the scope of the ecological risk issues, a variety of ecological expertises may be appropriate and necessary. This expertise may include terrestrial and aquatic ecological risk assessors, wildlife specialists, and/or biostatisticians. It is important that the RPM remain cognoscente of the diverse nature of the ecological resources of concern at their site, and that it is very unlikely that any one individual can adequately meet all the technical needs of the BERA.

3.1.3 Regulator/Interested Party Involvement

After the Tier 2 BERA is completed, a report documenting the methods and the results of the assessment will be prepared and distributed for regulatory approval. Because each site will have its own unique set of issues, concerns, and resources, there is no standard method or approach that can be applied uniformly across all sites to address all resources, contaminants and concerns, and each Tier 2 BERA will be unique (to one degree or another). Thus, there is always the chance that the regulators may not agree with some aspects of the Tier 2 BERA, and may therefore reject the conclusions of the report. To minimize the potential of such an occurrence, it is strongly recommended that in the Tier 2 BERA the RPM continue the early regulator involvement initiated in the Tier 1 SRA, with the goal of securing regulator concurrence and approval of the Tier 2 assumptions and methods as early in the Tier 2 process as possible. Additional information regarding regulator concurrence is presented in Section 3.2.7.

As in the Tier 1 SRA, it may also be appropriate to involve other interested parties early into the Tier 2 process. By including such parties as the public and environmental groups early, the RPM will be able to keep them informed about the progress of the BERA and help them understand why specific study designs were developed and implemented, how the data were evaluated and risks estimated, and how the consequent risk management decisions are made. This early involvement should serve to increase the likelihood of acceptance of the Tier 2 BERA results and risk management decisions.

3.2 Step 3a – Refinement of Conservative Exposure Assumptions

3.2.1 Objectives of the Step 3a Refinement

The Tier 1 SRA identified a number of contaminants that may be of potential concern with regards to ecological resources. As a result, a risk management decision was made to move the site into the Tier 2 BERA process (Figure 3.1). Because of the very conservative assumptions used in the Tier 1 SRA (see Section 2.4 of the *Ecorisk Process* portion of this web site), some of the contaminants of potential concern (COPC) identified for further evaluation in Tier 2 may actually pose an acceptable risk, and detailed evaluation of these COPCs may not be warranted.

The purposes of Step 3a are to reevaluate the COPCs that were retained from Tier 1 for further evaluation in a Tier 2 BERA and to identify and eliminate from further consideration those COPCs that were retained because of the use of very conservative exposure scenarios. Using less conservative (but more realistic) assumptions, the risk assessor recalculates the Tier 1 risk estimates and uses these new estimates to refine the list of COPCs identified by the Tier 1 SRA in order to remove some or all of the COPCs from further consideration.

3.2.2 General Approach for Step 3a Reevaluation

Step 3a involves the reevaluation of the Tier 1 SRA COPCs with less conservative but more realistic assumptions regarding exposure. Successful conduct of this step involves technical interactions with the regulators, and will require regulator concurrence before any COPC may be dropped from further evaluation. In addition, the reevaluation should also evaluate the Tier 1 risks with regard to background risks (Do site contaminant concentrations exceed background levels?), the magnitude and extent of the contamination and risk (Are high concentrations and risks widespread across the site or limited to discrete locations?), and bioavailability of the COPC (Could the COPC be in a chemical form that is less hazardous? Could the COPC be bound to sediments in such a manner that it cannot be taken up by biota?).

Conduct of the Step 3a reevaluation will generally follow these steps:

1. Revise exposure factor assumptions and recalculate doses and HQ risk estimates.
2. Identify COPCs with HQs < 1.0 and eliminate from further evaluation.
3. For COPCs with HQs > 1.0, compare maximum concentrations to background levels identify COPCs present at concentrations below background, and propose these for elimination from further evaluation.
4. For COPCs with HQs > 1.0, examine detection frequency, identify COPCs with low detection frequencies (and sufficient data for acceptable site characterization), and propose these for elimination from further evaluation.

5. For COPCs with HQs > 1.0, consider bioavailability, identify COPCs likely to be biologically unavailable, and propose these for elimination from further evaluation.

Each of these steps is discussed in further detail in the following sections.

3.2.3 Exposure Factor Revision and Dose and Risk Recalculation

Exposure factors refer to the parameters used in the Tier 1 SRA to model contaminant dose to the ecological receptor. Recall, a generalized model for estimating contaminant dose from food ingestion may take the following form:

$$Dose_{food} = \sum (C_{food} \times NIR \times FR_{food} \times SUF \times AE)$$

where:

$Dose_{food}$ = Daily contaminant dose from food, summed from all food items;

and the exposure factors are:

C_{food} = The contaminant concentration in each food item;

NIR = Normalized ingestion rate of food, calculated as the daily food ingestion rate divided by the body weight;

FR_{food} = Fraction of the food item in the total diet;

SUF = Site use factor, calculated as the area of contamination divided by the home range of the receptor; and

AE = Assimilation efficiency of the contaminant.

Conservative values were used for each of the exposure factors in the Tier 1 SRA, which resulted in very conservative risk estimates. For example, the Tier 1 SRA assumed an SUF of 1.0, meaning that the receptor spends 100% of its time at the site (i.e., in the area of maximum contaminant concentration). Obviously, actual exposure will be a function of the home range of the receptor (how large an area the receptor normally covers in its day-to-day activities related to feeding) and the areal extent of contamination. Suppose the ERA is evaluating a 10-acre site, and the ecological receptor of interest is the red-tailed hawk. The home range of this species has been reported to range from 150 to 1,400 acres, depending on geographic location (see Wildlife Exposure Factors in the *Methods and Tools* portion of this web site). Given the size of the contaminated area (10 acres), it is highly unlikely that this receptor would be spending 100% of its time on the site. However, that is the conservative assumption employed in the Tier 1 SRA. As an example, changing the SUF from 1.0 to a more realistic and scientifically based value of

0.07 (10 acres/150 acres) would reduce the Tier 1 dose estimate by a factor of about 15, and would similarly reduce the HQ risk estimate from food ingestion.

The above example addresses dose modeling only for the food ingestion pathway. Similar modeling would be conducted for water ingestion and incidental ingestion of soil and/or sediment, as appropriate for the receptor being modeled. In each of these models, similar revisions of the exposure factors would be made, new doses estimated, and HQs recalculated. In revising the exposure factors, the risk assessment team should identify a range of scientifically defensible values for the factors, and select the highest defensible values that could produce a HQ < 1.0 and thus support further COPC elimination. Regulators will likely be more acceptable of revised HQs based on small exposure factor revisions rather than those based on large revisions. For example, regulators may be uncomfortable in a HQ estimate for the red-tailed hawk based on a change in the SUF from 1.0 to 0.07, even though this later value may be scientifically defensible. However, an SUF of 0.5 may also result in a HQ < 1.0 and such a revision in the SUF from 1.0 to 0.5 may be much more acceptable to the regulators (and other interested parties).

The contaminant concentration also greatly influences the risk estimate. In the Tier 1 SRA, the maximum reported concentration is assumed to apply (i.e., the exposure point concentration) to the entire site, thereby maximizing receptor exposure. In many cases, the maximum concentration is likely representative of only a small portion of the site, with lower concentrations typical of the majority of the site. For the Step 3a reevaluation, the exposure point concentration may be based on a concentration other than the maximum, such as the 95% UCL of the mean. However, a statistically derived exposure point concentration (e.g., 95% UCL) requires a sufficient number of samples representative of the site to be meaningful.

Assimilation efficiency refers to the degree to which the contaminant is not only taken up by the receptor, but also retained and incorporated into body tissues. The Tier 1 SRA uses an assimilation efficiency of 1.0, meaning that 100% of the contaminant is incorporated into the receptor. This assumption does not take into consideration elimination of contaminants through feces or urine, biochemical detoxification mechanisms, or the nature of the contaminant in the food itself. For example, some contaminants do not move across the digestive system into the body, but are simply passed through without being taken up and are eliminated in urine or feces. The body may absorb other contaminants but cellular mechanisms quickly eliminate these or chemically alter them in a way that reduces toxicity. Finally, the contaminants may be located in specific portions of the food item that is not digested by the receptor. Birds of prey (such as hawks and owls) for example feed on small mammals but do not digest the bones or fur of their prey, and these materials are regurgitated (e.g., “owl pellets”). Thus, any contaminants associated with the fur or bones of the small mammals would likely not be assimilated.

3.2.4 Detection Frequency

The detection frequency refers to the percentage of total samples of a particular media in which the COPC was detected. In the Tier 1 SRA, detection frequency is not considered, and only the maximum reported concentration is used to estimate risk. However, if a particular COPC was detected only in a very small percentage of the samples collected, the risk identified in the SRA may be greatly overestimated. Chemicals that are infrequently collected may be artifacts related to sampling or analytical problems, or may be reflective of a contaminant hot spot (i.e., discrete area of very high contaminant concentration) rather than of widespread contamination. In such an instance, a decision to delete the COPC from further evaluation or to initiate a very selective cleanup may be appropriate. Elimination of COPCs on the basis of detection frequency is not uncommon in human health risk assessments, and additional discussion regarding criteria for evaluating detection frequency during COPC identification are provided in Section 5.9.3 of the EPA Risk Assessment Guidance for Superfund (RAGS): Volume I -- Human Health Evaluation Manual. RAGS Volume 1 can be viewed or downloaded at: http://www.epa.gov/superfund/programs/risk/ragsa/index.htm.

3.2.5 Bioavailability

In addition to considering the exposure factors, the risk assessor should also consider the bioavailability of the COPCs retained by the Tier 1 SRA. Bioavailability refers to the degree to which a contaminant in the media is available for uptake by a receptor. Bioavailability is assumed to be 100% in the Tier 1 SRA, however, several physical and chemical processes strongly affect bioavailability, and it may be much less than 100% for many contaminants. Processes affecting bioavailability may include degradation to other, less toxic forms (note that degradation may also result in products that are more bioavailable), complexation with other chemicals in the environment, ionization to other forms (which may be more or less bioavailable), precipitation, and adsorption. In addition, biodegradation and biotransformation represent biologically mediated processes that may also alter the bioavailability of a contaminant.

Because bioavailability may be affected by so many different factors and will vary from contaminant to contaminant, evaluation of this parameter is relatively difficult and problematic. For additional information regarding bioavailability, see the issue paper on this topic located in the *Issue Paper* portion of this web site.

3.2.6 Planning Considerations and Collection of New Data

As with the Tier 1 SRA, conduct of Step 3a in general should not include the field collection of new data. While revision of some of the exposure factors may be completed with the collection of a small quantity of additional data, securing information regarding some factors may be very costly and effort intensive to secure, and is therefore not warranted for Step 3a. The RPM should keep cost effectiveness in mind when discussing with the risk assessor plans for obtaining less conservative exposure factor values. Considerable information is available in the scientific literature regarding species-specific

exposure factors (such as home range, ingestion rates, and body weight), and these data may often be obtained through a relatively inexpensive literature search or by contacting appropriate experts in academia and various resource agencies. In contrast, site-specific determinations of exposure factors such as bioavailability, body weight, home range, and food ingestion rate will likely require extensive sampling of biota and sampling and chemical analysis of site-specific media. Similarly, in the absence of an available and acceptable background data set, the effort and cost required to collect and analyze sufficient samples to establish a defensible background level may be very high and therefore not cost-effective.

In some cases it may be appropriate to collect biological samples for tissue analysis in order to input site-specific values for contaminant concentrations in food (C_{food} in the dose models). This effort should be closely examined with regard to the amount of data (and associated costs) necessary to provide an acceptable and defensible data set and the benefits gained from the data. The risk assessor should conduct some 'back of the envelope' calculations to determine what effect site-specific data may have on the HQ estimates, and the RPM must consider whether the added cost and effort justify the predicted result. In general, the collection of samples for tissue analysis, if appropriate, would occur in the BERA after Step 3a. In all cases where site-specific data collection is being considered, the RPM should discuss with the regulators the availability of acceptable background values that could be used in Step 3a.

3.2.7 Exit Criteria, Potential Outcome, and Regulator Concurrence

3.2.7.1 Step 3a Exit Criteria

Step 3a includes two exit criteria:

1) If the reevaluation of the Tier 1 SRA conservative assumptions (including considerations of background, detection frequency, and other factors) **supports** an acceptable risk determination, then the site **exits** the ERA process.

2) If the reevaluation of the Tier 1 SRA conservative assumptions (including considerations of background, detection frequency, and other factors) does **not support** an acceptable risk determination, then the site **continues** in the Tier 2 BERA process.

3.2.7.2 Potential Outcome of Step 3a

Although the Step 3a exit criteria may allow for a site to completely exit the ERA process, it is highly unlikely that all the Tier 1 SRA COPCs will be removed from further evaluation in a BERA. A more likely outcome of the Step 3a reevaluation will be the elimination of a subset of the Tier 1 COPCs from further consideration on the basis of HQs < 1.0. Additionally, some COPCs with HQs only slightly exceeding 1.0 may be

proposed for elimination from further evaluation on the basis of background, detection frequency, and bioavailability considerations. The subsequent management decision will be to continue in the ERA process, but with the Tier 2 evaluation focusing on the smaller set of COPCs retained at the end of the Step 3a reevaluation and that are likely to be driving the ecological risk.

3.2.7.3 Regulator Concurrence

Regulator concurrence is obviously important in the risk management decision related to Step 3a. To secure this concurrence, it is critical that supporting data, evaluations, rationale, and documentation be provided to the regulators for their review. You will not be able to eliminate any of the Tier 1 COPCs from further evaluation without a scientific basis or rationale for doing so. For example, suppose the Tier 1 SRA modeled contaminant uptake by the American robin, with the assumption that the diet was 100% invertebrates. However, the Step 3a review of the scientific literature reveals that in some seasons, the robin's diet may be 80% vegetation in the form of seeds and berries, and over the course of the year the diet can be equally composed of vegetation and invertebrates. On the basis of this published scientific information, the diet was assumed to be 50% invertebrates for the dose modeling in the Step 3a reevaluation. It is important that this information is documented for the regulators. If such scientific support is not available and provided to the regulators, do not waste your time (and the regulators time) trying to force acceptance of the revised exposure factor assumption and any subsequent COPC elimination.

Even with scientifically defensible supporting information, regulator concurrence may not be forthcoming on all aspects of the reevaluation. Do not immediately argue disagreements with the regulators. It is important that the RPM seriously examine each component of Step 3a and weigh the potential benefits of actively arguing each of the reevaluations. In all cases of regulator disagreement, the RPM and the risk assessor should consider how the risk estimates might differ between what the risk assessor proposed and what the regulators propose. In some cases, there may be little or no difference in the risk estimate, and no benefit would be gained by arguing the issue. In other cases, a compromise value may be acceptable to both parties. In fact, such arguments could result in long-standing animosity between the Navy and the regulators, which should be avoided at all costs.

For example, suppose the regulators indicate that they will not accept an assumption of 50% invertebrates in the receptor's diet, but would accept a value of 75% (in lieu of the 100% used in the Tier 1 SRA). Is this difference worth arguing? If a revision to 75% results in an HQ < 1.0, then there is no point in arguing for a revision of 50%. Alternately, if the 75% revision does not reduce the HQ to less than 1.0, but a lower value at or below the scientifically defensible value of 50% does result in an HQ < 1.0, then further technical discussions and negotiations with the regulators would be warranted.

It is also important not to simply accept the regulator proposals. If the regulators propose alternative revisions to the Tier 1 SRA assumptions or refuse to consider any revisions

proposed by the Navy, the RPM should request the supporting rationale and scientific basis for the regulator proposal or stance. If supporting information is not provided, then it may be appropriate to disagree with the regulator's proposal or stance and retain the assumptions put forth by the RPM and the risk assessor. Again, consider the potential consequences of the regulator proposals on the risk estimates before making a decision of how to proceed.

In order to minimize potential disputes with the regulators on the Step 3a reevaluation, you should provide the revised Step 3a assumptions to the regulators as early in the process as possible, so that potential problems can be discussed and resolved before a major expenditure of effort and funding occurs. Contact NAVFAC/NFESC or your appropriate legal counsel for advice on issues dealing with regulator concurrence.

3.2.8 Documentation

Documentation of the Step 3a reevaluation should include two components: (1) letters, memos, or meeting minutes documenting concurrence regarding exposure assumptions, background considerations, detection frequencies, bioavailability, and any other negotiated topics or issues; and (2) a BERA report documenting the Step 3a reevaluation itself. The former may be documented in a Technical Approach Memorandum.

Because Step 3a occurs in Tier 2 and is part of the BERA, the report should be formatted to reflect the major components of Tier 2. A possible format may be:

- Introduction and background;
- Summary of the Tier 1 SRA analytical methods (including detection limits) and the existing data;
- Problem formulation, including a conceptual site model (as developed in Tier 1) and exposure assumptions;
- Description of the dose modeling methods, the HQ risk characterization approach, and the SEVs;
- Dose modeling and risk estimation results; and
- Risk management decision.

It is critical that the supporting data and rationale be clearly described for all revised exposure assumptions, as well as for other considerations, such as bioavailability and background.

3.3 Step 3b – Problem Formulation

If the site does not exit the ERA process on the basis of the Step 3a Reevaluation (see Section 3.2), the remaining steps of Tier 2 must be completed (Figure 3.1). Step 3b Problem Formulation focuses the scope and magnitude of the BERA and provides the basis for study design. The intent of Step 3b initially is to ensure that the assessment (and associated study design and data collection activities) focus on the important (i.e., the

most at risk) ecological and contaminant concerns for the site, and ultimately to provide for a scientifically defensible risk assessment that will support risk management decisions.

3.3.1 Objectives of Problem Formulation

The objectives of problem formulation are to develop an understanding of existing site conditions and to use this understanding to identify those components of the site that should be the focus of the Tier 2 ecological investigations and subsequent risk characterization.

Specifically, problem formulation identifies:

- The contaminant issues associated with the site, including the nature and extent of contamination and the toxicity of the COPCs retained after the completion of Step 3a,
- The relationships among environmental fate and transport processes,
- The ecological resources associated with the site,
- The ecological endpoints to be evaluated by the BERA, and
- The data gaps that must be addressed through site-specific investigations.

This information, in turn, serves as the basis of the data collection and analyses that follow. The risk assessment team will take this information and develop an integrated conceptual site model that describes the known or anticipated relationships among the COPCs and ecological resources, and link these to specific risk questions and hypotheses that will serve as the foundation for all the remaining steps of the Tier 2 BERA.

3.3.2 General Process for Problem Formulation

While the detailed aspects for problem formulation will vary from site to site owing to the unique combination of environmental and biological conditions present at any one location, problem formulation should address the following questions:

- Where is the primary source area of contamination?
- How are the COPCs being released into the environment?
- Are there areas of known or potential contamination other than the primary contaminant source area?
- What are the ecological entities (the assessment endpoints) that need to be protected?
- How are the contaminants getting to the assessment endpoints?
- What are the relationships between each COPC and its associated assessment endpoint?

In addressing these questions, problem formulation should follow these steps:

1) Identification of the primary contaminant sources,

2) Identification of the environmental fate and transport mechanisms and subsequent areas of contamination,
3) Identification of secondary contaminant sources,
4) Identification of exposed habitats and their ecological components,
5) Identification of exposure routes linking COPCs in the environment to specific ecological resources,
6) Identification of COPC-specific ecotoxicity data and linkage to exposed ecological resources,
7) Selection of assessment endpoints and the development of risk questions and hypotheses, and
8) Construction of a conceptual site model (CSM).

The following sections present specific information and guidance for conducting these activities.

3.3.3 Contaminant Sources and Environmental Fate and Transport

The first aspect of problem formulation is the identification of the primary contaminant source areas. Primary source areas are the locations and media where the original COPC spill or release occurred. Initial information regarding contaminant sources (and the nature of the release) was collected and evaluated as part of the Tier 1 SRA (see Section 2.3 of the Tier 1 guidance in the *Ecorisk Process* portion of this web site), and Step 3b should rely heavily on that information. During the Tier 1 SRA, each COPC was selected in part on the basis of a complete exposure pathway that links the contaminant in an environmental medium (e.g., sediment, water) to a potential ecological receptor. Thus, the primary contaminant sources for the site should be reasonably well known at this point in the Tier 2 process.

However, physical and biological processes may result in the release and transport of the COPCs from the primary source areas to other on-site and possibly off-site locations. These areas are the secondary contaminant source areas. Thus, potential transport mechanisms need to be evaluated and predictions made for what areas other than the primary source area may contain site-related COPCs. Examples of transport mechanisms that may move COPCs from one media and area to another may include:

- Volatilization of organics,
- Precipitation-driven erosion and runoff,
- Leaching, groundwater transport, and subsequent surface discharge,
- Wind-driven erosion, transport, and deposition of contaminated soil particles, and
- Transport by sediment-dwelling biota.

Beginning with the Tier 1 exposure evaluation (and supporting data and rationale) the risk assessment team should work with site characterization team members to identify likely transport mechanisms and areas of possible secondary contamination.

The interaction between the ecological risk assessment team and the site characterization team is important for several reasons. First, input from the characterization staff will assist the risk assessment team in identifying areas (other than the primary source areas) of potential exposure and risk to ecological resources. In turn, input from the ecologists, in the form of identification of specific habitats and media of interest, will help to integrate and coordinate environmental sampling activities, thereby reducing costs.

3.3.4 Ecological Resources – Linking Contaminants to Resources

Following the evaluation and identification of the primary and secondary source areas where COPCs are known or anticipated to occur, the risk assessment team should identify the ecological resources present at these locations. These resources represent those components of the ecosystem most likely to be exposed to site-related COPCs, and thus most likely to be at risk of adverse effects. Ecological resources may include individual populations, communities, or ecosystems.

As in the Tier 1 SRA, the risk assessment team should conduct a site visit to obtain first-hand information regarding the nature of the ecological resources at the site and at locations known or predicted by the fate and transport information to contain site-derived COPCs. Additionally, the risk assessor should evaluate the scientific literature and solicit information from federal and state natural resource agencies regarding the presence or absence of ecological resources at these areas. The result of this activity will be a list of ecological resources, such as species, communities, and habitats that are known or expected to occur at the site and thus represent potentially exposed ecological resources. It is from among this set of resources that specific ecological components will be identified for detailed evaluation in the BERA.

At this point in problem formulation, the risk assessment team will have identified the primary sources of contamination, the mechanisms by which the contaminants may be leaving the source areas and moving to secondary source areas, and the ecological resources present at these locations and potentially exposed to the site-related COPCs.

3.3.5 COPC Toxicity Evaluation

In addition to knowing where in the environment a specific COPC is or may be present, problem formulation requires information regarding the specific ecotoxicological mechanism of each COPC. While the range of COPC effects can include effects on reproduction, growth, mortality, behavior, and other responses, individual COPCs typically exhibit a few very specific mechanisms, which affect an exposed individual. In addition, contaminant effects may be restricted to particular environmental media and environmental conditions. For example, PCBs bioaccumulate and biomagnify and cause reproductive failure in top trophic level biota such as birds-of-prey and mammalian predators. In contrast, cadmium generally does not bioaccumulate or biomagnify in higher trophic level biota, and aquatic biota are most sensitive to its effects (e.g., cadmium damages gills, thereby affecting the ability to take up oxygen).

The risk assessment team should compile and evaluate information regarding the ecological toxicology and mode of action for each COPC retained after Step 3a. Again, COPC-specific toxicity information was collected as part of the Tier 1 SRA and the Tier 2 Step 3a *Reevaluation*, and these data should provide much of the information needed for Step 3b. This information should be evaluated together with the previously developed information regarding source areas, fate and transport mechanisms, and ecological resources to identify the most likely combinations of ecological resources, COPCs, and effects (i.e., reproductive impairment, reduced growth, mortality).

For example, suppose the results of the Tier 1 SRA and Tier 2 Step 3a reevaluation identify arochlor 1248 (a PCB) and cadmium as site-related COPCs. Examination of existing site-characterization data, together with discussions with the characterization staff indicates that the PCB has migrated from surface soil (the primary source area) to sediments located in an adjacent salt marsh (the secondary source area), and high levels of cadmium are present in the surface waters at the site. Ecological information obtained from a site visit, evaluation of the scientific literature, and data provided by the local Fish and Game Field Office shows that the salt marsh habitat supports a striped bass fishery and is a feeding area for fish-eating birds. On the basis of this information, the risk assessment team would identify arochlor 1248 as a COPC for fish-eating birds, while cadmium would be identified as a COPC for striped bass.

Information regarding COPC ecotoxicological mechanisms may be obtained from a variety of sources, including the scientific literature and published databases. A listing of some sources of ecotoxicological data can be found in the *Methods and Tools* portion of this web site.

3.3.6 Assessment Endpoints

Next, problem formulation must identify the assessment endpoints for the BERA. The 1998 EPA guidelines (not guidance) on ecological risk assessment (http://www.epa.gov/ncea/ecorsk.htm) define an assessment endpoint as an "explicit expression of the environmental value that is to be protected." In other words, the assessment endpoint represents an ecological entity (a particular resource or some aspect of that resource) that is to be protected from potential adverse effects associated with contaminant exposure. It is the assessment endpoint that represents the target of the BERA, and sets the basis for the development of specific ecological studies and data collection activities.

While identifying assessment endpoints, the risk assessment team should avoid endpoints that are too broad, vague, or narrow or that are inappropriate for the ecosystem requiring protection. Broad or vague endpoints make it difficult to develop studies to adequately evaluate risks to the endpoint. Rather, assessment endpoints should be specific and focused. For example, "protection of ecosystem function" would be an assessment endpoint for a contaminated grassland site that is too vague to be of value in the assessment process. The concept of "ecosystem function" encompasses a wide range of

parameters, while "protection" by itself does not provide a readily identifiable goal to evaluate. In contrast, "survival and reproduction of songbirds" provides a focused and directed assessment endpoint that will permit the identification of specific studies. This example clearly identifies the aspects (survival and reproduction) of the ecosystem component potentially at risk (songbirds) that will require detailed studies to evaluate.

Clearly defined assessment endpoints provide both direction and boundaries for the risk assessment. Because of the complexity of ecological systems, as well as the limited availability of information regarding contaminant-ecosystem interactions, the professional judgment and ecological knowledge of the risk assessment team becomes very important in the development of usable assessment endpoints.

3.3.6.1 Selection of Assessment Endpoints

Two elements are needed to adequately define an assessment endpoint:

- The identification of the valued ecological entity.
- The identification of the characteristic of that entity that is potentially at risk.

The valued ecological entity may include a particular species or population (e.g., the striped bass), an ecological functional group (e.g., fish-eating species), a community (e.g., benthic invertebrates), or ecosystem (e.g., marsh). The valued ecological entity should also be ecologically relevant (see below). Characteristics of interest may be associated with such parameters as survival, growth, reproduction, nutrient cycling, abundance and distribution, and diversity, and the selected characteristic should be susceptible to the COPCs.

Ecological relevance and susceptibility are critical in identifying scientifically defensible endpoints. They provide not only the ecologically based rationale for why a particular ecological entity should be protected (i.e., why it is considered important), and also a defensible rationale why other ecological entities were not selected as assessment endpoints.

3.3.6.2 Ecological Relevance

Ecologically relevant endpoints should reflect important ecosystem attributes that are related to helping sustain ecosystem structure and function. Examples of ecologically relevant attributes may include:

- Serve as a critical food source for a population,
- Provide unique nesting habitat for a species,
- Serve as the primary seed dispersal mechanism for forest trees, and
- Maintain a critically important ecological function, such as wetlands enhancing water quality.

Because of the perceived importance of these attributes, the risk concern is that a reduction or loss of one of these attributes due to contaminant exposure could result in a high degree of ecosystem disruption. Ecologically relevant endpoints may include any

level of organization, such as an individual, a population, a community, or a habitat, and may often include trophic levels. For example, in aquatic systems phytoplankton may be identified as an ecologically relevant ecological entity because it represent the base of the food chain and either directly or indirectly supports a variety of invertebrate and vertebrate biota. Birds-of-prey, such as the red-tailed hawk, may be considered ecologically relevant in terrestrial grasslands because they play an important role in controlling the abundance of lower trophic level biota such as herbivorous small mammals, which in turn affect the composition, productivity, and structure of plant communities.

Some ecological resources have societal importance, which also should be considered in evaluating relevance. Species protected under the Endangered Species Act may be at such low population levels that their importance to existing ecological conditions may be small, but they are important from a regulatory perspective. Other biota may be highly valued by the public for recreational or aesthetic reasons (e.g., white-tailed deer). It is important that the risk assessment team strive to identify societal species and evaluate their inclusion in the BERA. If these species are not considered in the BERA, the completed BERA may be challenged on the basis that it did not evaluate risks to a societally important species. Oftentimes an assessment endpoint may be identified that includes such species along with ecologically relevant endpoints, and the inclusion of the former species may have little effect on the effort and cost of the BERA.

For example, the salt marsh harvest mouse is a federally endangered species that occurs in coastal habitats in some portions of California. While selection of this species as an assessment endpoint might seem appropriate, the likely absence of sufficient ecological and toxicological information regarding this species, together with the restrictions on the sampling of this species make this species a inappropriate choice as an assessment endpoint. However, an assessment endpoint targeting the small mammal community would include the salt marsh harvest mouse. The ERA could then employ data from other, similar, small mammals, and studies could be designed using non-protected species.

Ecological relevance may not be immediately apparent, and its determination will rely in part on the expertise and professional judgement of the risk assessment team. Similarly, regulators and other stakeholders (such as Trustees) may have different opinions regarding the ecologically relevant entities of the ecosystem. For these species, importance may be related to resources under their jurisdiction.

3.3.6.3 Susceptibility

Susceptibility refers to how readily the endpoint may be affected by exposure to a COPC. Susceptibility can be affected by a number of factors, including:

- The mode of action of the COPC,
- The life-history characteristics of the potential endpoint,
- The life stage of the endpoint exposed to the COPC (age-dependent sensitivity), and
- The nature and magnitude of the exposure.

The COPC mode of action and toxicology are very important in the evaluation of susceptibility. Recall the cadmium example. In aquatic systems, cadmium adversely affects fish by directly damaging gills and affecting the ability to take up oxygen. Because of this mode of action, aquatic birds or mammals would not be considered as susceptible to the effects of cadmium as would fish.

Life-history characteristics refer to specific attributes that a species exhibits or requires in its normal life. For example, the life history characteristics of a species will include its home range (how big an area the species uses on a day-to-day basis), its habitat needs (e.g., old-growth forest, shallow water for feeding; cliff faces for nesting), and its diet (e.g., insects, nectar, small mammals). These characteristics should be compared to contaminant distribution and mode of action in order to identify which if any characteristic may be exposed and affected by a COPC. For example, the ruby-throated hummingbird has a very specific diet, namely nectar. Thus, this species would not be expected to be susceptible to COPCs bound to sediment, or with soil COPCs that are not taken up by plants and incorporated into nectar by plants. Thus, on the basis of susceptibility, the hummingbird would not be considered as an appropriate assessment endpoint for these types of contaminants.

Life stage refers to the developmental stage of an individual, i.e., whether it is an adult, juvenile, larva, or egg. Many chemicals exhibit different affects on different life stages of an organism, and some life stages may be more sensitive than others. Thus, the risk assessment team should consider the potential life stages of biota when selecting endpoints. For example, fish larvae may be particularly sensitive to a particular COPC, and may thus be more appropriate as assessment endpoints than adults of the same species. In contrast, a COPC may not affect adult waterfowl but strongly affect development of embryos.

Exposure refers to the contact of the endpoint with the COPC of concern. Exposure may result from direct contact with contaminated media, ingestion of contaminated food and media, inhalation of vapors or contaminated media, or any combination of these mechanisms. Considerations of exposure should also take into account the frequency (how often) and duration (how long) of exposure. For example, a species may only occur at the site during a specific time (i.e., during spring migration) or may be present year-round. Exposure should be evaluated together with life stage considerations and life history characteristics.

3.3.6.4 Outcome of Assessment Endpoint Selection

Following determination of ecological relevance and susceptibility, the risk assessment team will identify one or more assessment endpoints to be addressed in detail in the BERA. There is no minimum or maximum number of assessment endpoints. The number selected will be a function of the nature and extent of the COPCs, the ecological resources exposed to the COPCs, and the ecotoxicity and mode of action of the COPCs. If multiple media (surface water, soil, sediment) and habitats (e.g., wetland, upland forest, riparian corridor, salt marsh) are associated with the areas of contamination, there

will most likely be multiple assessment endpoints. Table 3.1 provides some examples of assessment endpoints.

3.3.7 Risk Questions and Hypotheses

At this point in problem formulation, the risk assessment team has completed a number of activities. It has assembled and evaluated data related to the distribution and concentration of the site-related COPCs, and worked with the site-characterization team to identify known or expected environmental fate and transport mechanisms. The risk assessment team has conducted a site visit, and together with data from other sources, identified ecological resources known or expected to utilize the areas of contamination. Furthermore, COPC toxicity data have been collected and evaluated, and exposure routes to ecological resources identified. On the basis of these evaluations and information, the risk assessment team has identified the assessment endpoint(s) for the site.

The risk assessment team will use this information to develop risk questions and risk hypotheses for the site. The risk questions integrate the information developed up to this point in problem formulation into questions about the relationship among assessment endpoints and their responses when exposed to site contaminants. In general terms, a risk question can be stated as: *Is exposure to a site contaminant causing adverse effects to the selected assessment endpoint?*

Specific risk questions should be developed for each assessment endpoint and COPC, and these will serve as the basis for later activities in the Tier 2 BERA (i.e., study design, data analysis, and risk characterization).

In contrast to risk questions, the risk hypotheses propose mechanisms and identify specific assumptions regarding the effects of site-related COPCs on assessment endpoints. These proposed mechanisms are based on existing data from the site together with assumptions about how exposure may be occurring and what the affects may be. While the risk question asks, “Are there adverse effects?”, the risk hypotheses present the how, where, and why of COPC effects on ecological resources. Once hypotheses are identified, the risk assessment team designs specific investigations to evaluate the hypotheses and draw conclusions regarding risks to the ecological assessment endpoints. The proposed mechanisms and assumptions represent data gaps that must be addressed to answer the risk questions and characterize risks to the assessment endpoints. Table 3.2 presents some examples of risk hypotheses.

3.3.8 The Conceptual Site Model

At this point in Step 3b, the risk assessment team has identified COPCs and ecological resources, evaluated exposure routes, fate and transport mechanisms, evaluated COPC toxicity, identified assessment endpoints, and developed risk questions and hypotheses. The final step of problem formulation is the integration of this diverse information into a ‘big picture’ description of all that is known and/or expected about the site. This ‘big picture’ is the conceptual site model (CSM).

3.3.8.1 What is a Conceptual Site Model?

The CSM is a written description and visual representation of the known, expected, and/or predicted relationships between the site contaminants and the ecological resources of concern (the assessment endpoints). The CSM describes (1) what is known about the site with regard to contaminant sources (environmental media), (2) the environmental fate and transport mechanisms and pathways along which the contaminants may be moving from the original source area to other locations and media, (3) the exposure routes along which the contaminants move from environmental media to the ecological receptors, and (4) the assessment endpoints.

Although the CSM is basically a diagram, it should also include supporting text that presents the risk hypotheses that describe the relationships among the contaminants and the assessment endpoints. While there is no standard format for a CSM, these models typically take the form of flow diagrams, with boxes identifying contaminant sources, environmental media, and ecological receptors or endpoints, and arrows identifying contaminant pathways among media and biota (Figure 3.2).

3.3.8.2 Why Use A Conceptual Site Model?

The CSM represents a valuable planning and communication tool for interactions among the project team and with regulators and the public. In diagrammatic form the CSM presents complex relationships in a straightforward, direct manner, easily conveying information about:

- Current site conditions with regard to contaminant sources and assessment endpoints,
- Site assumptions regarding COPC fate and transport, exposure, and effects, and
- Existing information and data gaps.

3.3.8.3 Constructing the CSM

The CSM may be simple or complex, depending on the nature of the site and associated ecosystem(s). In the Tier 1 SRA, a preliminary CSM was prepared to focus the understanding of the site on the basis of available data. This CSM was relatively simple (Figure 3.3) and identified, in general terms, the following aspects of the site:

- Known and suspected contaminant sources,
- Known or expected fate and transport mechanisms,
- Preliminary receptors of concern and generic assessment endpoints, and
- Suspected exposure routes.

The Tier 2 CSM builds on this earlier CSM by incorporating additional detail and focus to describe:

- Fate and transport of individual COPCs,
- Exposure routes linking individual COPCs to specific assessment endpoints, and

- Movement of COPCs through the ecosystem to the assessment endpoints.

The complexity of the model will depend on the nature of the site and the nature and number of COPCs and assessment endpoints. For very large and complex sites, it may be necessary to develop several models and submodels to adequately represent the site. Figure 3.4 presents an example of a Tier 2 CSM. Note that this example represents the aquatic (lower) portion of the Tier 1 CSM depicted in Figure 3.3. A similar Tier 2 CSM could be developed for the terrestrial portion of the Tier 1 CSM. A PC-based software package for constructing CSMs can be found in the *Methods and Tools* portion of this website.

3.3.9 Scientific Management Decision Point, Concurrence, and Documentation

At the conclusion of problem formulation, the risk assessment team will have identified assessment endpoints, developed risk questions and hypotheses, evaluated the COPCs with regard to ecotoxicity and modes of action, and developed one or more conceptual site models. This information forms the basis for the subsequent design and implementation of site-specific investigations.

3.3.9.1 The Step 3b Scientific Management Decision Point

Before proceeding to the next step in Tier 2, namely Study Design and DQOs (Figure 3.1), the outcome of problem formulation must be presented to the regulators for review and concurrence. This concurrence represents the SMDP for Step 3b. Specifically, the SMDP consists of agreement between the Navy risk assessment team and the regulators on:

- COPCs and their distributions,
- Assessment endpoints,
- Exposure pathways, and
- Risk questions and hypotheses.

3.3.9.2 Regulator Concurrence

To secure concurrence on these items, it is critical that the supporting data, evaluations, and rationale used to select assessment endpoints and develop the risk questions and hypotheses be provided to the regulators for their review. If such supporting information is not provided, it is highly doubtful that regulator concurrence will be forthcoming.

The Navy risk assessment team should work closely with the regulators and other interested parties during all aspects of problem formulation, and should strive to do so in a cordial, team-like atmosphere. The regulators should not be viewed as adversaries, but rather as partners in the BERA process. However, even with supporting information, regulator concurrence may not be forthcoming on all aspects of problem formulation. It is important that the Navy risk assessment team closely examines each aspect of problem formulation and weighs the potential benefits of actively debating any items in disagreement. For example, if the regulators indicate that they would like to see several

additional assessment endpoints evaluated in the BERA, the Navy risk assessment team should consider how these would affect the scope and outcome of the BERA. In some cases, there may be little difference in subsequent study design and data collection activities, and little benefit would be gained by arguing the issue.

Alternately, the inclusion of additional assessment endpoints may not be necessary to evaluate risks to assessment endpoints, and/or may require the collection and analysis of data that will not add to the BERA but will incur greater costs and require more time for completion. If the regulators propose alternative or additional assessment endpoints, the RPM should request the supporting rationale and scientific basis for the regulator proposal. Disagreements will most likely be related to the interpretation of ecological relevance. If supporting information justifying the need for additional or alternative assessment endpoints is not provided, then it may be appropriate to retain the assessment endpoints originally put forth by the Navy risk assessment team.

In order to minimize potential disputes with the regulators on problem formulation, you should strive to work closely with the regulators throughout the process. Initiate discussions with the regulators regarding assessment endpoints as early in the process as possible. The Navy has established an Ecological Risk Technical Assistance Team (ERTAT) to provide technical support to Navy sites conducting ecological risk assessments. Click here for information on how to obtain assistance from this group. Contact NAVFAC/NFESC or your appropriate legal counsel for advice on issues dealing with regulator concurrence.

3.3.9.3 Documentation

Documentation of regulator concurrence may take a number of forms, such as a signed letter of concurrence from the regulators, a letter from the Navy to the regulators, or formal meeting minutes identifying concurrence. It is important that the concurrence is documented, so that previously agreed upon issues (such as the assessment endpoints to be evaluated) are not revisited in ongoing BERAs as a result of changes in either Navy or regulator staff. This documentation will serve to protect both the Navy and the regulators from unnecessary changes and delays in the BERA.

While no specific document is required at the conclusion of Step 3b, the outcome of problem formulation and all supporting information and rationale should be documented in a technical memorandum or report. Preparation of such a memorandum or report will serve two purposes. First, it will provide a concise technical package for submittal to the regulators for review and concurrence. Secondly, this documentation will serve as the basis for the problem formulation portion of the BERA report that will be prepared at the conclusion of Tier 2. At this point in Tier 2, the BERA exits Step 3b and proceeds to Step 4 Study Design (Figure 3.1).

3.4 Step 4 - Study Design and the DQO Process

During Step 3b *Problem Formulation* the risk assessment team addressed problem formulation and identified assessment endpoints, risk questions, and risk hypotheses

related to contaminant exposure and effects. The risk assessment team developed a CSM describing the known or expected relationships among the COPCs and assessment endpoints at the site, and any data gaps associated with these relationships. Following the successful completion of problem formulation the BERA enters Step 4, *Study Design and the DQO Process* (Figure 3.1).

Step 4 of the Navy ERA process represents the identification and design of the scientifically defensible site-specific investigations necessary to address the risk hypotheses and risk questions previously developed. Activities associated with Step 4 include:

- Identification of specific data needs.
- Selection of assessment endpoint-specific measurement endpoints.
- Determination of the type and amount of the needed data.
- Identification of the acceptable levels of uncertainty related to the data needs.
- Identification of specific methods for collecting and analyzing the data.
- Selection of the appropriate risk characterization approach.
- Selection of specific study methods (i.e., toxicity tests, field surveys, tissue analyses).

The development of a scientifically defensible study design is accomplished through the application of the Data Quality Objectives (DQO) process. There is no standard 'boiler plate' study design that can be applied to all sites. Each study design will be unique to the site under evaluation, and will be a function of the assessment endpoints, the COPCs, the risk hypotheses, and the DQOs developed for that site. This portion of the website provides guidance to assist the RPM during the study design portion of the BERA.

3.4.1 Objectives of Study Design

The primary objective of *Study Design* is to produce a draft Work Plan (WP) and a draft Sampling and Analysis Plan (SAP). These plans identify the scientifically defensible investigations that will be used to evaluate the exposure and effects of site-related COPCs to the assessment endpoints developed during problem formulation. These investigations must be designed to:

- Identify cause-and-effect relationships between the COPCs and the assessment endpoints.
- Support a defensible risk characterization.
- Support a risk management decision.
- Develop preliminary remediation goals (if necessary).

Activities during *Study Design* include the identification of measurement endpoints for each assessment endpoint and the development of assessment endpoint-specific studies using the Data Quality Objectives (DQO) process. Proper study design is crucial to focusing the BERA data collection activities (and associated effort and cost) on those data most critical to supporting a risk management decision. Without such a focusing activity, an ERA may be designed that collects the wrong data for the right problem, or the right data for the wrong problem; both cases waste time and funds and do not support the decision-making process. This focusing is accomplished through the application of the DQO process to study design, and results in a draft WP and draft SAP.

3.4.2 Measurement Endpoints

During problem formulation (see Section 3.3) the risk assessment team identified one or more assessment endpoints for the BERA. The assessment endpoint represents the ecological resource and an associated function of quality that is to be protected from potential adverse effects of the exposure to site-related COPCs. The measurement endpoint, in turn, represents that characteristic of the assessment endpoint that will be directly measured in the BERA and used to establish cause-and-effect relationships between the COPCs and the assessment endpoint.

Measurement endpoints can include measures of exposure and/or effects. For example, an assessment endpoint may be "maintenance of reproduction of Coho salmon at level similar to that in populations not exposed to site-related COPCs." Measurable characteristics of fish reproduction that may be suitable as a measurement endpoint include the number of eggs spawned per nest, the mortality of eggs exposed to contaminated sediment or water, the percentage of eggs per nest that hatch, the percentage of larvae surviving to adulthood, the number of spawning adults, or population age structure. One or more of these characteristics may be adversely affected by exposure to site-related COPCs, and thus may serve as endpoints that serve to measure the effects of exposure. A measurement endpoint may also be a measure of exposure, such as the COPC concentration in sediment, water, or soil, in food, or in body tissue. One of the goals of study design is to identify the measurement endpoints most appropriate for evaluating risks to the assessment endpoints.

3.4.2.1 Relationship between the Measurement and Assessment Endpoints

The risk assessment team should evaluate each potential measurement endpoint with regards to how strongly it is related to the assessment endpoint. Consider the earlier example that identified an assessment endpoint as "maintenance of Coho salmon reproduction at levels similar to that in populations not exposed to site-related COPCs." One of the measurable characteristics identified as a potential measurement endpoint included the number of spawning adults. While the number of spawning adults directly affects reproduction, the number of spawning adults can be affected by a variety of factors not related to the site and COPC exposure. For example, commercial/recreational fishing pressure on the population under evaluation may be greater than on other populations. Similarly, changes in predation pressure or a disease outbreak may have

reduced the adult population prior to its return to the spawning areas. Access to spawning areas may have been affected by the construction of dams or a natural stream blockage (e.g., landslide). Any of these factors may result in a reduction in the number of spawning adults, and none are associated with site-related COPCs. Therefore, the "number of spawning adults" may not represent a very good measurement endpoint.

Alternately, some measurement endpoints may be more strongly related than others to the assessment endpoint may. Because of the role of other factors, the "number of spawning adults" represents a measurement endpoint that is weakly related o the assessment endpoint ("maintenance of Coho salmon reproduction at levels similar to that in populations not exposed to site-related COPCs"). In contrast, the "mortality of eggs exposed to contaminated media" is a measurement endpoint that is very strongly related to the assessment endpoint and thus represents a very good measurement endpoint.

3.4.2.2 Relationship to the Risk Hypotheses and Risk Questions

The measurement endpoint must address the risk questions and hypotheses that were developed during *Problem Formulation*. Risk questions are specific questions about the relationship between an assessment endpoint and its response to COPC exposure (Section 3.3.7). In the case of the Coho salmon example, the risk hypothesis may be that contaminated sediments originating as runoff from the site are impacting salmon reproduction by increasing egg mortality. The associated risk question may be "Are current COPC concentrations in site sediments toxic to Coho salmon eggs?" The measurement endpoint should target the risk question and hypothesis, and in this example would be the level of mortality of eggs exposed to contaminated sediments.

3.4.3 Selecting Measurement Endpoints

A critical aspect of selecting measurement endpoints is that it must be directly related not only to the assessment endpoint but also to the mechanism of toxicity and the exposure route of the COPC under evaluation. Selection of measurement endpoints should also consider the implementability of the measurement endpoint.

3.4.3.1 Mechanisms of Ecotoxicity

The measurement endpoint must be related to the toxic mechanism(s) identified for each COPC during *Problem Formulation* (Section 3.3.5). The Navy risk assessment team should evaluate the mechanism of toxicity relative to the assessment endpoint, and select measurement endpoints that clearly link the endpoint with an effect. For example, if a COPC is identified to damage developing eggs, a measurement endpoint that evaluates the percentage of eggs hatching may be appropriate. In contrast, an endpoint that evaluates larval survival to adulthood would be inappropriate (the COPC does not affect larval survival) and would not provide usable data for evaluating risks to the assessment endpoint (Coho salmon reproduction) from COPC exposure.

3.4.3.2 Exposure

Each measurement endpoint must reflect the exposure pathways identified during *Problem Formulation* and used to select the assessment endpoints. The risk assessment team should use the conceptual site model, which identifies the exposure pathways linking each COPC to each appropriate assessment endpoint, and select measurement endpoints that incorporate the exposure pathways. For example, for the Coho reproduction assessment endpoint, measurement endpoints associated with the direct exposure of eggs to sediment or water may be more appropriate than ones associated with exposure of adults through food consumption. However, it is important that the risk assessment team consider exposure together with the mechanism of toxicity. Exposure of adults through food ingestion may be very important to maintaining reproduction if the COPC adversely affects egg production or egg viability.

3.4.3.3 Implementability

The selection of measurement endpoints should also consider the implementability of the endpoint. While a particular endpoint may be very appropriate, collection of the required data may be very difficult due to technological constraints (specific data collection and handling requirements or analytical instrumentation needs) or environmental constraints (data collection dangerous or extremely difficult). Implementability may also be affected by budget and schedule constraints. Additional information regarding implementability evaluation of measurement endpoints is provided in Section 3.5 *Verification of the Field Sampling Design*.

3.4.3.4 Regulator Concurrence Regarding Endpoint Selection

Because of the variety of measurement endpoints that may be selected for any one assessment endpoint, there could be significantly differing views as to the most appropriate measurement endpoints to be used for an assessment endpoint. It is therefore crucial that the measurement endpoints developed by the Navy risk assessment team be presented to the regulators (and other appropriate stakeholders such as Natural Resource Trustees) for their review and concurrence. The Navy should identify not only the endpoints themselves, but also the rationale supporting their selection (i.e., relationship to the assessment endpoints). The Navy should not solicit suggestions regarding appropriate measurement endpoints from the regulators and other interested parties without first internally developing the measurement endpoints. The RPM should request that any regulators or stakeholders proposing measurement endpoints provide the scientific rationale for their recommendations. The Navy risk assessment team should then review these before any decision is made to incorporate the suggestions into the study design. This review should focus on:

- The strength of the relationship between the assessment endpoint and the measurement endpoint.
- The availability and requirements of the data collection methods.
- The applicability of the methods to generate data for developing PRGs.

- Whether the method will generate data that can be used to support a risk management decision.

3.4.4 Types of Studies

Individual studies developed for the Tier 2 BERA will fall into two general categories, studies that characterize assessment endpoint exposure to site-related COPCs, and studies that characterize the effects of the COPCs on the assessment endpoints. In human health risk assessments, exposure is typically characterized using a single approach, dose modeling, and potential effects are characterized by comparing the modeled exposure to COPC-specific dose concentrations that represent specific effects. In contrast, ERAs can employ a variety of approaches for characterizing exposure and effects, which can be placed into four categories: toxicity tests and population/community field evaluations which characterize effects, and tissue residue studies and dose modeling which characterize exposure. These are discussed in detail below, additional information is provided elsewhere on this website (*Methods and Tools*).

3.4.4.1 Studies of Effects

Toxicity Tests

A toxicity test evaluates effects by directly exposing test biota to environmental media across a range of contaminant concentrations and examining a specific response, and provides a direct measure of adverse effects of COPC-contaminated site media. Toxicity tests are widely used to evaluate surface water, soil, and sediment, and standardized protocols are available for a variety of these tests. The test biota are typically laboratory-raised strains (to reduce natural variability in response). For the Tier 2 BERA, the test biota should serve as surrogates of site biota and be representative of the assessment endpoint.

Test endpoints may be related to mortality, growth, or reproduction. The specific endpoint will be based on the COPC mechanism of toxicity and the assessment endpoint under evaluation. During testing, biota undergo either short-term (acute) or long-term (chronic) exposure to a range of contaminant concentrations. The results are compared to the effects observed for simultaneously conducted control and reference toxicity tests. Control tests are conducted under identical test conditions but using laboratory prepared media with no COPC present. Reference tests are conducted under identical test conditions using media from a reference location with no COPC present. Additional information regarding toxicity testing can be found in the *Methods and Tools* section of this website.

To adequately capture effects, the test biota should be exposed to a range of COPC concentrations that include both effects and no-effects concentrations. Exposure to such a range will permit development of dose-response curves that in turn can be used to identify NOAEL and LOAEL risk levels (Section 3.7.2). If toxicity tests are included in the study design, the risk assessment team must develop justification for the test itself (its

relationship to the assessment endpoint), the exposure period (acute vs chronic), the exposure range, and the test biota (surrogates for site biota and relationship to the assessment endpoint). The team must also ensure that the design will permit the development of PRGs (Section 4.0) if the result of the Tier 2 BERA indicate that remediation is warranted.

Population/Community Field Evaluations

Field evaluations are studies conducted at the site and under natural conditions rather than in the laboratory, and that target resident biota rather than laboratory strains. These studies evaluate responses of specific characteristics of populations or communities to actual COPC exposures at the site. The Tier 2 BERA will typically include one or more field studies. In these studies, investigations are conducted to evaluate ecological relationships and characteristics of biota resident the site under evaluation and at uncontaminated (reference) areas. Field studies may evaluate any number of ecological parameters, including but not limited to mortality, behavior, growth, reproduction, nutrient processing, population and community structure and function.

3.4.4.2 Studies of Exposure

Tissue Residue Studies

Tissue residue studies involve the collection of biota directly from the site and analysis of their tissues to determine COPC concentrations. Such tissue studies are the only way to determine actual exposure of site biota to the site-related COPCs. Although the study design is conceptually straight forward (go out and collect biota and send to a laboratory for COPC analysis), there are a number of issues that must be carefully considered in designing such studies. These include:

- Ease of capture of the target biota.
- Which tissues are needed (whole body, fillet, blood, and internal organs).
- Restrictions in collecting biota (permit requirements).
- The amount of tissue necessary for each laboratory analytical method.
- Tissue handling, shipping, and storage protocols.

Dose Modeling

Dose modeling is commonly used in ERAs to predict exposure to higher level organisms such as mammals and birds. Dose modeling employs mathematical models together with species-specific ecological data and site-specific COPC concentrations to predict the amount of COPC to which the modeled receptor may be exposed (as a dose) on a daily basis. Recall that dose models were employed in the Tier 1 SRA to provide very conservative estimates of exposure (Section 2.4), and in the Tier 2 Step 3a SRA refinement (Section 3.2.3). Similar dose models would be developed for the Tier 2 BERA, but would likely include more realistic food chains and food webs. In addition, tissue sampling may be employed to provide site-specific food item concentrations.

3.4.5 Early Considerations of Risk Characterization and PRG Development

Risk characterization is the last step of the Tier 2 BERA (Step 7, Figure 3.1). During that step, the risk assessment team will use the study results to characterize risks posed by the site-related COPCs to the assessment endpoints. The RPM then uses this characterization to make a management decision regarding the need for remediation. If the decision is that remediation is warranted, the risk manager will need to have PRGs that address the risks identified to the assessment endpoints. In order to effectively characterize risks and develop PRGs (if necessary), these activities must be considered during, and incorporated into, study design.

There are several approaches for characterizing risks, each requiring study results to be of a specific format or type. In many cases, the risk characterization will be based on the evaluation of multiple lines of evidence from a variety of investigations. For example, the measurement endpoints for an assessment endpoint may include a toxicity test, tissue analyses, and a measure of community structure. Each of these measurement endpoints has a unique metric that is not directly or easily transferable across all the measurement endpoints. For the toxicity test, the results may be expressed as % mortality, tissue analyses present results as a tissue concentration (mg COPC/kg tissue), and the community metric may be a diversity index value. As a consequence, it is critical that the risk assessment team determines the approach to be used for risk characterization, and integrate the characterization needs with the study design.

Study design should also consider how PRGs would be developed, if necessary. The development of site-specific PRGs will require that the BERA studies be designed so that it will be possible to identify NOAEL and LOAEL media concentrations. The identification of these values will require studies to be developed along COPC concentration gradients at the site, thereby allowing for the development of dose-response curves and site-specific ERVs. These values, in turn, are employed to develop the PRGs. (Section 4.3).

If the study design does not take into account the requirements for risk characterization, the use of the study results in risk characterization will be difficult and problematic, and may lead to a risk characterization that is based more on professional judgement than on scientifically defensible analyses. Similarly, if the potential need to develop PRGs is not considered during study design, then it will be difficult if not impossible to develop site-specific PRGs to support remedy development and evaluation. Risk characterization is discussed in detail in Section 3.7. The development of site-specific PRGs is discussed in Section 4.3.

3.4.6 Reference Site

Biological data collected from the field will reflect the response of the measured parameter of concern to current and past environmental conditions at the sample location or from other locations, which the sampled biota may have previously visited. For

example, at any point in time plant biomass at a location will be the result of current climatic conditions and soil conditions (chemistry and structure) as well as of climatic conditions in previous years. Thus, biomass measured in one season may be due more to drought conditions that occurred during the previous growing season rather than current conditions.

At Navy sites undergoing an ERA, it is critical that the risk assessors differentiate between results due to site-related COPCs and results due to other, non-site related conditions. In order to differentiate between these results, the study design should include the use of a reference site. A reference site can be an unimpacted area of the site or a nearby site that is ecologically and environmentally as similar as possible to the site undergoing the BERA. The reference site provides baseline environmental and biological data that is considered to be representative of the site in the absence of the site-related COPCs. By comparing the site data to the reference data, the risk assessor can then determine to what extent the measured response is due to COPC exposure at the site versus some non-site specific factor. For example, data collected from the BERA site indicate a low diversity in the benthic invertebrate community that occurs in contaminated sediments at the site. Viewed on its own, the data could be interpreted that the site COPCs have adversely affected the benthic invertebrate community. However, comparison of the site data to data collected from a reference location that is not affected by the site contaminants reveals a similarly low diversity of the benthic community at the reference site. This comparison now leads to the conclusion that some other factor, not related to the site COPCs, is responsible for the reduced species diversity, and that the site COPCs are not responsible for the impacted benthic community.

Additional information regarding reference sites is provided in Section 3.5.3, and in the *Methods and Tools* portion of this website.

3.4.7 Data Evaluation Considerations

The study design must also include identification of the approaches that will be employed to analyze the data generated by each measurement endpoint. For many methods, specific statistical analyses will be necessary to determine whether the observed or measured response is truly different for a measured control or reference area response. There are a variety of statistical methods and tools available for data analysis, and the specific statistic used will be a direct function of the study design, the nature of the data, and the degree to which a difference will be considered as significant. Because of these many factors, it is important that the Navy risk assessment team include statistical support, and that this support be brought in during study design and not after the data have been collected. Statistical input will aid in the determination of necessary sample sizes, identification of appropriate statistical approaches (t-test, ANOVA, non-parametric methods), and determination of levels of significance.

3.4.8 Focusing the Study Design – Use of the DQO Process

3.4.8.1 Data Quality Objectives and the DQO Process

Data Quality Objectives (DQOs) are qualitative and quantitative statements that define the type, quality, and quantity of data necessary to support a defensible risk management decision. In other words, the DQOs identify when to collect samples, where to collect the samples, the number of samples to be collected, practical constraints for collecting the samples, and the level of uncertainty that acceptable to the decision maker.

The DQO process consists of seven sequential that lead to the development of an optimized data collection plan. In this process, the output of each step is used as input for the next. The process may also be iterative, with the output of one step resulting in the reconsideration of earlier steps. The steps of the DQO process, shown in Figure 3.5, are:

Step 1: State the Problem - Clearly describe the problem to be studied.
Step 2: Identify the Decision - Identify the decision that requires data to address the risk questions and hypotheses.
Step 3: Identify the Inputs to the Decision - Identify the information and data needed to support the decision.
Step 4: Define the Study Boundaries – Specify the conditions (time periods, spatial areas, and situations) to which the decision applies and within which the data will be collected.
Step 5: Develop a Decision Rule – Develop a logical "if…then" statement that defines the conditions by which alternative decisions will be selected.
Step 6: Specify Acceptable Limits on Decision Errors – Define, in statistical terms, the acceptable error rates based on the consequences of making an incorrect decision.
Step 7: Optimize the Design – Evaluate the results of the previous steps and develop the most resource-effective sampling and analysis design for generating data that will satisfy the DQOs.

3.4.8.2 Goals and Objectives of the DQO Process

The objectives of the DQO process are to:

- Clarify the study objectives,
- Define the appropriate type of data to collect,
- Determine the most appropriate conditions from which to collect the data, and
- Specify the acceptable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

The outputs of the process, namely the DQOs, are then used to develop a sampling design that is appropriate for evaluating risks to the assessment endpoints, that is scientifically defensible, and that will support a risk management decision for the site. The DQO process accomplishes this by designing studies which avoid the collection of data that do

not address the assessment endpoints, risk questions, or risk hypotheses and are thus of little or no value in subsequent decision-making for the site.

Use of the DQO process improves project planning efficiency by promoting positive communication between the RPM and the risk assessment team, focusing the BERA objectives to a clear action-oriented decision; and ensuring that decisions are made at the desired level of confidence. Use of the DQO process also promotes defensibility of the data by providing a record of what data is needed before data collection begins and the rationale for needing that data, and by establishing a logical rationale for making a remedial decision.

The products of the DQO process are clear, concise statements that define the data quality criteria and sampling design performance specifications. These criteria define "how good" the data should be, and the degree of uncertainty in the data that will be acceptable. These statements will identify such items as the study design, the number and locations of samples to be collected, the analytical detection limits, sample collection methods, and analytical methods.

By focusing the data requirements and optimizing the design for data collection, the DQO process should facilitate rapid review and approval by regulators and other stakeholders, enhance communication with the public, and hopefully limit the degree to which worst case, prescriptive requirements and assumptions are included in the BERA.

3.4.8.3 The Decision Rule

The output of the first four steps of the DQO process are integrated into a statement, the decision rule, that describes the logical basis for making a decision. A decision rule is an "If…, the…" statement that defines the conditions that would cause the decision-maker to choose an action. In other words, it establishes the exact criteria for making a choice between taking or not taking an action. There are three main elements to a decision rule:

- The parameter of interest (e.g., an environmental medium such as sediment);
- An action level; and
- Alternative actions (the decision choices).

For example, a decision rule associated with a toxicity test may be: "**If** the results of the toxicity test of site sediment indicate a mortality level that is 20% or more that the mortality level determined for the reference site sediment, **then** the sediment will be considered to pose an unacceptable risk and action will be taken to remediate the sediment; otherwise no remediation will be implemented." In this example, the parameter of interest is sediment, the action level is the measured level of mortality compared to a reference site, and the alternative actions are remediation or no remediation.

3.4.8.4 Application of the DQO Process

The DQO process is a tool for planning action-oriented environmental data collection activities, and results in the development of a SAP for the site. Without the problem focus

and decision specifics that the DQO process generates, there is no mechanism to ensure that the SAP will identify the desired type and quality of data needed to support the site decision/risk questions. The DQO process is not an option for the BERA but a requirement and serves as the basis for study design.

Application of the DQO process begins in Tier 1 and continues through Tier 2. Note that DQO Steps 1 and 2 have effectively been completed through the completion of the Tier 1 SRA, the Tier 2 Step 3a *Reevaluation* and Step 3b *Problem Formulation*. For example, Tier 1 and Step 3a identified COPCs (and associated media) that may be posing unacceptable ecological risks (DQO Step 1). The decision (DQO Step 2) facing the RPM is whether and how to remediate the site in order to reduce risks to acceptable levels.

For successful implementation of the DQO process**,** involve the appropriate technical staff, regulators, and stakeholders as early in the process as possible. These include public stakeholders, regulators, the risk assessment team, and possibly a statistician. The extent of involvement of these people will depend on the scope and scale of the BERA and a greater involvement of the public and regulators may be appropriate for very complex or controversial sites.

Additional information regarding the DQO process can be found in the *Methods and Tools* portion of this web site; also see the *Issue Papers* section of the web site. For those interested in obtaining training on the DQO process and its application to environmental problems, CECOS provides a course on this topic. See the CECOS home page for schedule information on the DQO course.

3.4.9 Step 4 Scientific Management Decision Points

At the conclusion of Step 4 Study Design, the RPM, the risk assessment team, and the regulators should be in agreement on the following items:

- The measurement endpoints and the rationale supporting each endpoints selection;
- The specific site investigation methods for each measurement endpoint; and
- The methods to be used for evaluating and interpreting the data.

These items, along with the concurrence among all appropriate parties, are documented in draft BERA Work Plan (WP) and Sampling and Analysis Plan (SAP), and it is these plans that serve as the SMDPs for Step 4. The RPM should identify the WP and SAP as required deliverables to the Navy team and contractors responsible for conducting the BERA.

3.4.10 Documentation

Documentation of the study design should include the following information:

- The assessment endpoints and the rationale for including those assessment endpoints in the BERA.

- The risk questions and decision(s) to be made.
- The types of data needed to support risk questions/decisions and supporting rationale.
- The environment (and/or what time frame) that must be represented by the data.
- The measurement endpoints and an explanation of how the measurement endpoints will be used to answer the risk questions.
- The level of decision certainty.

3.4.10.1 The Work Plan (WP)

The WP should document the results of problem formulation (Tier 2 Step 3b) and identify the additional investigations that will be necessary to evaluate risks. The EPA Superfund ERA guidance identifies the general components for the WP as:

- A general overview and background of the site's environmental setting, ecology, and site history (developed during Tier 1 and Tier 2 Step 3b);

- A summary and analysis of previous site investigations and conclusions (developed during Tier 1 and Tier 2 Steps 3a and 3b);

- A CSM (developed during Tier 1 and Tier 2 Step 3b), including identification of the potential exposure pathways selected for analysis, the assessment endpoints (Tier 2 Step 3b), the risk questions and hypotheses (Tier 2 Step 3b), and the measurement endpoints (Tier 2 Step 4);

- Identification of additional site studies needed for the BERA (developed during Tier 2 Step 4); and

- A description of assumptions used and the major sources of uncertainty in the CSM and existing information (developed during Tier 2 Step 3b).

The WP presents only a general description of the studies to be conducted during the BERA. Details regarding these studies are presented in the SAP.

3.4.10.2 The Sampling and Analysis Plan (SAP)

The SAP typically consists of two components: a Field Sampling Plan (FSP) and a Quality Assurance Project Plan (QAPP). The FSP details the sampling and data-gathering procedures to be used for the BERA. The QAPP details the policies, organization, and quality control protocols necessary for achieving the BERA objectives.

The Field Sampling Plan (FSP)

The FSP presents the detailed sampling protocols for each study to be conducted for the BERA as outlined in the WP. The FSP should provide sufficient detail so that a sampling team unfamiliar with the site would be able to gather the required samples and/or field data using the procedures and information presented in the FSP. Specific components of the FSP should include for each measurement endpoint the following information:

- Sampling type and objectives;

- Sampling location, timing, and frequency;
- Sample designation;
- Sampling equipment and procedures;
- Sampling equipment and procedures; and
- Sampling handling and analysis.

The Quality Assurance Project Plan (QAPP)

Specific components of the QAPP typically include:

- A project description;
- Designation of quality assurance (QA) and quality control (QC) responsibilities;
- Identification of the DQOs;
- Sample collection and chain of custody procedures;
- Record keeping procedures;
- Audits; and
- Quality control reports.

Formal QA/QC procedures exist for some ecological study methods such as toxicity tests. These procedures typically specify information such as the handling and disposal of hazardous wastes, sources and culturing of test organisms, use of laboratory controls and study replicates, instrument calibration, data evaluation, and records keeping. In contrast, similar QA/QC procedures are not as well developed for many field-based evaluations such as biotic surveys.

3.5 Step 5 – Verification of the Field Sampling Design

At the conclusion of Step 4 (*Study Design and DQO Process*), a draft WP and SAP were prepared that identify the measurement endpoints and their associated data collection and analysis methods. The Tier 2 BERA now enters Step 5, *Verification of the Field Sampling Design* (Figure 3.1). While the study design used the DQO process to ensure that data collection will focus on the data necessary to complete the BERA and support a risk management decision, there is still the possibility that successful implementation of some or all of the study design may not be possible. Step 5 evaluates the study design with respect to implementability and allows for changes in the WP and SAP before expenditure of effort and costs related to field mobilization and data collection and analysis.

3.5.1 Objectives of Verification

The objectives of field verification are to identify and resolve study design problems before full implementation of the SAP. Problems may occur for a variety of reasons. For example, the study design might require the collection of 100 grams of banded killifish tissue for chemical analysis. However, the collection of such an amount of tissue may not be possible or practical because of the low abundance of this species in the study area, difficulty in collecting the fish (e.g., they are hard to catch), or safety issues associated with the site (such as presence of unexploded ordnance [UXO] in the required

sampling area). If such problems are identified, the study design is revised to resolve the problem. In this example, study design revisions may include the collection of a different fish species that is more common or easier to collect and meets the original data need and DQOs identified during study design. Alternately, study revision may identify the use of a different analytical method that requires smaller tissue amounts that can be collected but provides data that meets the study needs and fulfills the DQOs.

3.5.2 Study Design Problems and Verification Approaches

Four types of problems are commonly encountered during implementation of the study design:

- An inappropriate reference area was chosen.
- The proposed methods and study specifications are incompatible with site conditions.
- Site media are incompatible with toxicity test organisms.
- The DQO assumptions of variability and distribution type are not verifiable via a pilot study collecting limited amounts of data.

The feasibility and practicality of the proposed sampling design should be verified through a combination of site visits and the use of site-specific pilot studies. In a pilot study, limited amounts of data are collected before full-scale implementation of the SAP, and aspects of this preliminary sampling effort are evaluated for potential problems. Pilot studies represent the best approach for verifying that the study design is feasible and practical and that the collected data will meet the specified study objectives and support a risk management decision for the site. The risk assessment team should evaluate all components of the study design, including:

- Reference site characteristics,
- Sample size,
- Sampling location and timing,
- Sample collection methods,
- Toxicity testing conditions, and
- Data analysis techniques.

3.5.2.1 Reference Areas

During study design, reference areas were identified for all of the individual studies (see Section 3.4 for guidance regarding selection of reference areas). To be appropriate, reference areas should be as physically, chemically, and biologically similar to the site as possible, with the exception of the presence of COPCs. This similarity should include, but not be limited to, such parameters as:

- Habitat,
- Biota,
- Topography,
- Hydrology,

- Climate,
- Geology, and
- Water quality.

During study design, reference areas were likely selected in part on the basis of historical information present in maps, reports, and other data sources. However, environmental conditions are always changing, and the historical data may no longer be representative of current conditions. To verify the appropriateness of the reference areas, the risk assessment team (the Navy and its contractors, the regulators, and other interested parties as appropriate) should visit the proposed areas. Pilot studies collecting preliminary data on habitat, water quality, and other appropriate parameters should be used to verify that the requirements for reference area selection have been met and the selected area is appropriate.

3.5.2.2 Proposed Methods or Study Specifications Are Incompatible with Site Conditions

In some cases, it may not be possible to implement a specific method as identified in the SAP because of physical conditions of the site. For example, the SAP may specify that the upper 6 inches of sediment must be collected for use in a toxicity test, and that sediment samples are to be collected with an Ekman dredge grab sampler. Grab samplers are devices designed to penetrate the sediment by virtue of their own weight, and they have spring- or gravity-activated closing mechanisms. An Ekman dredge is very efficient in soft sediments, but it is inefficient in harder sediments and in areas with moderate or stronger current. A site visit and attempts to collect sediment reveal that the bottom sediments are primarily rocky, and it is not possible to collect the sediments with the specified collection technique (i.e., the Ekman dredge). In this example, the SAP will have to be revised to include an alternative collection method - a different type of dredge that can effectively sample harder, more rocky sediments.

Conditions at some sites may make it difficult to meet the study specifications (such as sample size) identified in the SAP. For example, to evaluate reproductive effects of COPCs on songbird populations, the SAP specifies that egg-hatching success must be evaluated for 50 nests of a particular species in order to provide the required sample size for statistical analyses. Depending on the size of the nesting population (10 pairs vs. 1,000 pairs of nesting birds) and the ease of sampling (nests are located on cliff faces vs. in low-growing shrubs), it may or may not be possible or practicable to collect the required sample size. Study revisions may include selection of a different species for sampling or the selection of another approach for evaluating COPC effects on reproductive success. Any such revisions must meet the data needs and DQOs identified during study design and initially agreed upon by the Navy and the regulators.

3.5.2.3 Site Media Are Incompatible with Study Methods

In some cases, the site media itself may be incompatible with the proposed testing procedures. This problem will often be associated with toxicity tests using site media, and is generally referred to as “confounding factors.” For example, the amphipod *Leptocheirus plumulosus* is often used in toxicity tests of sediment-dwelling

invertebrates. This species is very sensitive to sediment grain size and requires a specific sediment type for survival. If the sediment collected from the site and used in the toxicity tests is not of the appropriate grain size, *Leptocheirus* will not survive. The interpretation of these results may result in incorrectly linking the observed mortality to the COPC rather than to factors unrelated to the COPC. Pilot studies will help determine the applicability of the proposed test method, and revisions may include relocating media sampling to locations with suitable media, or selecting an alternative toxicity test that uses a different test organism. Additional information on confounding factors may be found in the *Issue Papers* portion of this guidance website.

3.5.2.4 DQOs Assumptions Regarding Data Variability Are Not Met

The number of samples and the sample locations identified in the SAP are based on assumptions about the variability and distribution of the data to be collected. If the variability is higher than expected, more samples or replicates must be collected to meet the DQO specifications for acceptable uncertainty (see Section 3.4). Pilot field studies can be used to collect limited amounts of data to estimate variability and determine if the DQO assumptions on variability are met. For example, perhaps the SAP specifies that 20 similarly sized adult females of a particular fish species must be collected from five locations at the site. A pilot study is implemented, and evaluation of the preliminary data indicates that the variability in fish size is much greater than assumed. Therefore, it will not be possible to collect 20 adult females of the specified size. Thus, the SAP will have to be revised and an alternative study design developed. Samples collected during the pilot study may also aid in the determination of sample variability, providing the necessary information for statistically determining appropriate sample sizes.

3.5.3 Scientific Management Decision Point – the Approved Work Plan and Sampling and Analysis Plan

If verification is not possible, then either the study design or the acceptable limits on decision errors (DQO Step 6, see Section 3.4) must be revised. Revision of the decision error limits may result in making a wrong decision (i.e., concluding that the site does not require remediation because it poses no risk when in reality it does, or concluding that remediation is necessary when in fact it is not). Because the consequences of a wrong decision may be quite serious, increasing error acceptability should be done with caution, and its possible consequences should be carefully evaluated.

In most cases, problems identified during the pilot studies can be addressed by revising the study design. This revision may take the form of changes in the number or location of samples to be collected, or it may require the replacement of one proposed study with a completely different study. It is important to remember that any revisions to the SAP, whether major or minor, must also undergo field verification, and any modification of the SAP must be done in consultation with the risk assessment team and the regulators.

The SMDP for Step 4 was an approved draft WP and SAP. For Step 5, the SMDP is the approved and signed final WP and SAP. Once the WP and SAP are finalized and

approved, the studies may be implemented as part of the next step (Step 6) of the Tier 2 BERA process (Figure 3.1).

3.6 Step 6 – Site Investigation and Data Analysis

3.6.1 Objectives of Site Investigation and Data Analysis

Upon completion of the WP and SAP, Step 6 (*Site Investigation and Data Analysis*) of the Tier 2 BERA process is initiated (Figure 3.1). This step is the implementation of the studies specified in the SAP. During site investigation, data are collected to characterize the exposure and the effects of site-related COPCs to the assessment endpoints. The data analysis portion of Step 6 evaluates the collected data. Together, the data and the results of the analyses will be used in Tier 2 Step 7 (*Risk Characterization*) to characterize ecological risks posed by the COPCs to the assessment endpoints.

3.6.2 Potential Difficulties during Site Investigation

It is important that all data collection conducted during Step 6 be done in full accordance with the specifications identified in WP and SAP. Because potential problems would have been identified and resolved through the Step 5 *Field Verification* (see Section 3.5), implementation of the SAP should be straightforward. However, because the data collection activities are occurring under field conditions, situations may arise that can adversely affect the site investigation and require additional modifications to the BERA schedule and possibly to the SAP. The situations most likely to impact site investigation include (1) changes in site conditions and (2) discovery of unexpected contamination.

3.6.2.1 Changes in Site Conditions

Sometimes site conditions change because of such unexpected events as severe weather or human activities. A severe or lengthy storm can dramatically change hydrological conditions at a site, affecting the successful sampling of biota and media. For example, in response to high water and increased flow in streams as a result of a storm, fish often move from their preferred habitats and seek shelter in areas protected from the current. In some cases, these areas may be quite far from the preferred habitat of the species and from the sampling locations specified in the SAP. In addition, high water levels and stream flows may hinder or prevent sampling and pose a safety risk to the field crew. In such cases, site investigation activities should be delayed, which may or may not impact the overall timeline for completing the BERA.

Of similar or even greater concern is that an unavoidable delay in data collection may be sufficiently long that the sampling period specifications in the SAP can not be met. For example, the SAP may specify that fish samples be collected during the spawning season. However, high water conditions resulting from unexpectedly heavy spring runoff prevented sampling until after spawning had been completed. Thus, it was not possible to collect the required data during the specified time.

Besides natural conditions, human activities may also affect implementation of some or all aspects of a specific study design, either by limiting access to sampling locations or physically disturbing the sampling area. For example, access may be limited to a specified sampling location may be limited because of unexpected training or range activities, while construction of shoreline stabilization structures may eliminate nearshore spawning areas identified for sampling. As with the previous example, such delays may affect the overall project schedule or completely prevent collection of specified data.

3.6.2.2 Unexpected Contamination

Situations may arise in which analysis of data collected during site characterization and after the approval of the WP and SAP indicate the presence of unexpected contamination. This unexpected contamination may take the form of new areas of contamination but the same COPCs, or the discovery of a previously unexpected contaminant. For example, site characterization data may indicate that contaminated sediments are present farther downstream then predicted by fate and transport evaluations during problem formulation. Because these areas were not previously considered during problem formulation and study design, it is unlikely that the sampling scheme in the SAP addresses these new areas of contamination. The characterization data may also reveal the presence of a previously undetected contaminant that has not been evaluated in the Tier 1 SRA or in earlier steps of Tier 2.

3.6.3 Revising the WP and/or SAP

Delays in site investigation activities should be immediately evaluated with respect to potential impacts on the study design specifications. If the delays are expected to be of short duration, the site investigators may still be able to collect the specified data and meet the study DQOs. In this case, no revision to the SAP will be necessary. Alternatively, if the delays are anticipated to be of sufficient duration so as to preclude meeting the study specifications, then some manner of revision to the SAP will be necessary. The nature of the revisions will be a function of the specific study affected and the nature of the delay.

The risk assessment team should reevaluate the SAP in the event of discovery of a greater extent of contamination than previously known or anticipated. Unless the sampling locations identified in the SAP include these new areas of contamination, the SAP will require revision to include these additional areas (and potentially additional media). The previously specified sample sizes, data collection methods, and analytical methods should also be evaluated for possible revision.

It is unlikely that the methods and study specification identified in the SAP will be appropriate to address risks from newly discovered contaminants. Before initiating any revisions to the SAP, the risk assessment team should evaluate the data for the new contaminants within the context of the Tier 1 SRA and, if appropriate, with the Step 3a *Reevaluation* of Tier 2 (Figure 3.1). If the new contaminant is retained as a COPC on the basis of these evaluations, it should be further evaluated within the context of the CSM to

determine if the current assessment endpoints, risk questions, and risk hypotheses are sufficient to incorporate the new COPC. If not, the WP (including the CSM, assessment endpoints, and risk questions and hypotheses) will require revision.

All modifications to the WP and/or SAP should be discussed among the risk assessment team and the regulators, and agreed upon by all appropriate parties before any of the revisions are implemented.

3.6.4 Step 6 Scientific Management Decision Point

No SMDP will be necessary for Step 6 unless there are changes to the WP and/or SAP. In the event of revisions caused by changing field conditions, the SMDP will be an approved and signed revised final WP and/or SAP. Unless extensive revisions are needed, the SMDP may take the form of an approved and signed addendum to the current final WP and/or SAP. In the event of a new contaminant, the SMDP should include the results of the additional Tier 1 SRA and Tier 2 Step 3a evaluations, documentation of Navy and regulator concurrence on these evaluations, and an approved and signed revised WP and SAP.

3.7 Step 7 – Risk Characterization

At the conclusion of Step 6 (S*ite Investigation and Data Analysis*), the studies identified in the SAP have been completed and data collected on the exposure and effects of COPCs on the assessment endpoints. These data include physical and chemical characterization data, toxicity data for each COPC, and ecological data. In Step 7 *Risk Characterization* (Figure 3.1), these data and results are integrated into one or more conclusions about the risks to the assessment endpoints and are used to answer the risk questions developed during problem formulation. This risk characterization provides the basis for the RPM to make a risk management decision about the site.

3.7.1 Objectives of Risk Characterization

Risk characterization has two primary objectives:

- To estimate risks to the assessment endpoints, and
- To aid the RPM in making an appropriate risk management decisions for the site.

To meet these objectives, risk characterization consists of three major components:

- A risk estimate,
- A determination of ecological significance and risk acceptability,
- An uncertainty analysis.

3.7.2 Risk Estimation

Three methods are commonly used to estimate ecological risks:

- Hazard Quotient (HQ) method,
- Lines-of-Evidence (LOE) method, and
- Weight-of-Evidence (WOE) method.

3.7.2.1 Hazard Quotient (HQ) Method

The HQ method is a simple approach that is commonly used in HHRAs to evaluate risks from noncarcinogens. This same approach is used in the Tier 1 SRA (see Section 2.5) to estimate ecological risks. The HQ is a ratio of a measured or modeled exposure to an effect concentration considered to represent a "safe" environmental concentration or dose. In the Tier 2 BERA, the "safe" effects concentration is termed an ecotoxicity reference value (ERV) and is analogous to the screening ecotoxicity value (SEV) used in the Tier 1 SRA (see Section 2.5.2). The term toxicity reference value (TRV) is often used when using the HQ method to estimate risks to wildlife species, and this term is directly analogous to the ERV.

Computational Basis

The HQ is calculated using the following equation:

HQ = (Exposure Estimate) ÷ ERV

where:

HQ	=	the hazard quotient.
Exposure Estimate	=	either an environmental concentration or a modeled dose, and
ERV	=	ecotoxicity reference value.

Values of the HQ may range from less than 0.1 to ∞, with values less than 1.00 considered indicative of acceptable risk (this is the same risk acceptability criterion used in the Tier 1 SRA). HQ risk estimates should be calculated for each COPC-assessment endpoint pair. When used to estimate risks for modeled COPC doses, HQs should be calculated for each modeled exposure pathway (i.e., food ingestion, water ingestion, dermal uptake, etc.) and for all pathways combined. Calculation of HQ values for individual pathways may permit identification of the pathways and media contributing the greatest risk to the assessment endpoint and thus help to focus potential remediation alternatives.

The HQ approach has a number of features that make it particularly useful for estimating risks. It is relatively simple, quick, and inexpensive. Because risk acceptability is based

on comparison of the calculated HQ value to a single critical value (HQs < 1.0 indicate acceptable risks, while HQs $\geq$ 1.0 indicate unacceptable risks), it is very easy to communicate the results not only to the regulatory community but also to the public.

The Hazard Index (HI)

Some risk assessors (especially in human health evaluations) sum the HQs for all COPCs to provide a single risk estimate for all the contaminants. That risk estimate is termed a Hazard Index (HI). Because of the large degree of uncertainty regarding the cumulative effects of multiple contaminants, NAVFAC does **not** recommend the use of HIs unless adequate rationale is provided to support the summation of the individual HQ values. The EPA Superfund ERA guidance similarly states that the HI should only be used for COPCs with the same toxic mechanism. If the regulators request HIs, the RPM should request supporting rationale from the regulator regarding the validity of summing HQ values. Furthermore, if a HI is to be calculated, HQs should be summed **only** for COPCs that have similar mechanisms of ecotoxicity. COPC-specific ecotoxicity information will have been compiled earlier in Tier 2 as part of the toxicity evaluation conducted during problem formulation (see Section 3.3).

Developing Site-Specific ERVs

Although some standardized values are available for use in the Tier 1 SRA (see Section 2.5.2), such values are typically not available for the Tier 2 BERA. Although some values may be derived from the scientific literature, these values will not be site-specific, and any risk estimates derived from these values will have a greater uncertainty than risk estimates derived using site-specific ERVs. Thus, it is recommended that site-specific ERVs be derived for the Tier 2 BERA.

To develop site-specific ERVs, studies must be conducted along contaminant gradients at the site and that capture the range of concentrations that include no effects and adverse effects. Such studies will provide both exposure and effects data from which dose-response curves may be generated. These dose-response curves, in turn, can be used to identify no-observed-adverse-effects level (NOAEL) and lowest-observed-adverse-effects-level (LOAEL) concentrations that bound an ERV risk range (Figure 3.6). The NOAEL concentration is the highest concentration at which chronic exposure causes no observed adverse effects; adverse effects begin to be observed at exposure concentrations greater than the NOAEL. The LOAEL concentration is lowest concentration of a contaminant that is observed to cause an adverse effect in an exposed individual; no adverse effects occur at exposures to lower concentrations.

It is important to note that the collection of data along concentration gradients and the subsequent development of ERVs may not always be possible, especially for studies other than toxicity tests. For example, it may be possible to identify sampling locations that will provide a soil concentration gradient, and a dose-response curve could be generated using any of a variety of laboratory toxicity tests (such as earthworm survival). However, if the measurement endpoint is nesting success of grassland birds and nest sites do not occur along a concentration gradient, it likely will not be possible to develop a dose-response curve and derive ERVs for nesting success of the grassland birds.

Estimating Risks Using Site-Specific ERVs

Risks are estimated by comparing site COPC concentration (collected as part of the nature and extent site characterization) to the ERV range and calculating a HQ risk estimate. Areas of the site with COPC concentrations exceeding the LOAEL concentration will be considered to pose unacceptable risks, while areas with concentrations less than the NOAEL concentration will be considered to pose acceptable risk. The range between the NOAEL and LOAEL represents conditions for which risks are uncertain, and these areas will require a more detailed evaluation of risk and more regulator input.

Note that the development of site-specific ERVs will require careful study design during project planning in order to generate effect data along concentration gradients. If the study design will not permit the generation of such data, then it will not be possible to develop the dose-response curves necessary to identify site-specific ERV ranges. The derivation of site-specific ERVs must be identified in the SAP and agreed upon by all parties.

3.7.2.2 Lines-of-Evidence (LOE) Method

The Tier 2 BERA will typically evaluate a number of measurement endpoints for each assessment endpoint identified in problem formulation. However, the results of these evaluations may not readily support risk estimation using the HQ approach. The risk assessment team must integrate the different types of data and results for the measurement endpoints into a risk estimate for each assessment endpoint. The LOE method represents an approach for integrating these dissimilar data and results into a risk estimate. The LOE approach evaluates all qualitative and quantitative information for each measurement endpoint (i.e., toxicity tests, uptake modeling, field studies, tissue concentration measurements, etc.) and applies professional judgment to provide a single qualitative risk estimate for the assessment endpoint. If an LOE approach is to be used, the approach must be specified in detail in the SAP and approved by all appropriate parties.

General Approach

In the LOE approach, the risk assessment team evaluates the study results for each assessment and measurement endpoint together with considerations of which studies take precedence (which studies are considered most important, which studies have the least uncertainty) as determined during study design and through the DQO process. This approach relies heavily on the professional judgment of the risk assessment team.

There is no right or wrong amount of evidence, although the more lines of evidence available, the more likely it will be that conflicting or inconclusive results can be resolved. The number of available lines of evidence will be driven by the nature of the assessment endpoint being evaluated and the specific studies and DQOs developed and agreed upon by the risk assessment team and the regulators during problem formulation.

For each assessment endpoint, the risk assessment team will estimate risk on the basis of:

- The strength of each measurement endpoint,
- The magnitude of response for each measurement endpoint, and
- The degree of concurrence among the measurement endpoints.

Measurement endpoint strength is based on a number of factors, including the following:

- The relative importance of each line of evidence (Is mortality more important than a reduction in biomass?),
- The quality of the data (To what extent were the DQOs met?),
- The degree to which the measurement endpoint is related to the assessment endpoint (The assessment endpoint is the protection of nutrient cycling in site soil, and the measurement endpoints are nutrient-acquiring enzyme activity in soil bacteria, microbial biomass, litter decomposition rates), and
- The uncertainties associated with the measurement endpoint (Can the results be attributed to other factors such as natural variability?).

The magnitude of the response is based on the strength of the observed or predicted effect. For example, if the measurement endpoint were germination of lettuce seeds in site soils (a common toxicity test), the degree to which germination is reduced would be a measure of the magnitude of the response.

The degree of concurrence refers to the extent to which the various measurement endpoints indicate adverse effects to the assessment endpoint. In an earlier example, three measurement endpoints were evaluated to assess risks to nutrient cycling in site soils (the assessment endpoint). If the results of all three measurement endpoints indicate adverse effects (or all three show no adverse effects), concurrence would be considered high.

Regulator Concurrence

Risk characterization using the LOE approach depends strongly on the professional judgment of the risk assessors evaluating the results of the various studies. Professional judgment plays an especially important role in the LOE approach when the lines are in conflict. For example, suppose three lines of evidence are to be considered in the risk characterization. One line is based on sediment toxicity testing and indicates high sediment toxicity to the test organisms. A second line of evidence is based on the composition of the benthic community inhabiting the site sediments; these results indicate a community similar in species composition but with slightly reduced abundance as at the reference area. The final line of evidence is based on the presence or absence of the COPC in site sediments at a concentration known to adversely affect aquatic biota. Sediment analysis indicates COPC concentrations to be present at levels similar to background levels. If the toxicity LOE is considered to be most important, then the interpretation of the LOEs might be that the sediments pose an unacceptable risk. Alternately, the absence of an adversely impacted benthic community together with measured COPC concentrations at acceptable levels may be considered to outweigh the toxicity test results and support an acceptable risk determination.

Because the interpretation of a given set of study results can vary among risk assessors, it is important that the interpretation of specific results in an LOE framework be discussed with the regulators early in the ERA process. The Navy team should develop a framework that identifies all possible combinations of results and interpretations of those results. This framework should be developed during Step 4 Study Design of the Navy ERA process, and presented to the regulators for review and discussion, and concurrence should be documented in the draft WP and SAP. These early discussions with the regulators should minimize disagreements with the regulators at the conclusion of the Tier 2 BERA regarding result interpretation and risk characterization.

3.7.2.3 Weight-of-Evidence Method

Although the LOE method integrates the results of various studies into a single risk estimate, that estimate is largely qualitative in nature. The WOE method represents a variation of the LOW approach that provides a procedure for integrating the results of multiple measurement endpoints into a single risk estimate, but in a more quantitative manner.

General Approach

For a given assessment endpoint, the WOE method:

- Assigns a numerical weight to each measurement endpoint,
- Categorizes the magnitude of the response in each measurement endpoint, and
- Graphically identifies concurrence (based on numerical weight and response magnitude) among measurement endpoints.

The risk estimate for the assessment endpoint is based on the degree of concurrence among the measurement endpoints. Each measurement endpoint is evaluated against 10 attributes related to applicability to the assessment endpoint and the COPC response, data quality, and study design and implementability. For example, toxicity testing using site media and with a mortality endpoint may be weighted higher than a study that evaluates growth. Measurement endpoints with the highest quality for the most attributes are assigned the greatest numerical weight. Each measurement endpoint is evaluated for the magnitude of its response (high, low, undetermined), and those endpoints exhibiting strong or obvious responses are assigned a greater weight than measurement endpoints with marginal or ambiguous responses. Concurrence among measurement endpoints is estimated by plotting each measurement endpoint in a weight-response matrix. A greater risk is attributed to an assessment endpoint when there is agreement among multiple measurement endpoints, while risks are considered lower for assessment endpoints that exhibit little concurrence among the measurement endpoints.

A free web-based tool for developing the WOE weighting scheme and graphing concurrence can be found at http://web.ead.anl.gov/woe/. Additional information on the WOE method can be found in Menzie et al., 1996 (Human and Ecological Risk Assessment Vol. 2, pages 277-304).

Regulator Concurrence

As with the LOE method of risk characterization, use of a WOE approach should be identified to the regulators early in the ERA process. The Navy team should develop a weighting scheme that clearly defines the criteria on which each measurement endpoint is to be weighted. Because of the more quantitative nature of the WOE method, the weighting scheme should be supported by a more scientifically defensible rationale than the employed in the LOE method. The WOE weighting scheme should be developed during Step 4 Study Design (see Section 3.4), and following discussions and concurrence with the regulators should be included in the WP and SAP.

3.7.2.4 Potential Issues with the LOE and WOE Methods

Both the LOE and WOE methods rely strongly on the professional judgment of the risk assessment team, and professional judgment may vary considerably among different risk assessors. Both LOE and WOE methods will require close interactions among the Navy risk assessment team, the regulators, and other appropriate parties in order to reach concurrence on weighting schemes, determinations of endpoint strength, and interpretations of response magnitude and endpoint concurrence.

In general, confidence in the risk estimate derived using either approach will be directly related to the number of measurement endpoints evaluated for each assessment endpoint. The fewer measurement endpoints, the more difficult it will be to resolve conflicting results and derive a risk estimate.

In contrast to the HQ method, neither the LOE nor WOE method provides a numerical risk estimate. The LOE method develops a completely qualitative estimate. Although the WOE method employs a numerical weighting scheme as part of the risk estimate approach, it also provides a qualitative risk estimate. The final WOE risk estimate is based on a visual (qualitative) interpretation of the concurrence among the measurement endpoints.

3.7.2.5 Probabilistic Risk Analysis (PRA)

General Approach

In the HQ method, risks are estimated on the basis of a single point-estimate of exposure, while the LOE and WOE methods evaluate multiple measurement endpoints to derive qualitative risk estimates. In contrast, probabilistic risk analysis (PRA) approaches utilize statistical distributions of exposure and effects data to estimate a range of risk probability.

The most commonly used probabilistic risk analyses involve the use of probabilistic modeling. Probabilistic modeling attempts to quantify the likelihood that a receptor will receive a given dose or exposure. The most common type of probabilistic modeling uses a Monte Carlo procedure, and a variety of software packages are commercially available for performing this analysis. In this procedure, data distribution curves are developed or assigned to the values of one or more input parameters of a dose model (Figure 3.7). The

model is then run multiple times (e.g., 1,000 times), each time with a single value for each input parameter randomly selected from the data distribution curve for that parameter. After all the model runs are completed, the model outputs from each run are compiled to develop a probability distribution curve for the dose estimate. A probability distribution curve of HQs can then be generated to provide an estimate of the likelihood of any single risk estimate being realized.

Caution should be taken when considering the use of a Monte Carlo analysis. Distribution curves are not typically available for most of the input parameters employed in dose models of ecological receptors, primarily because of the lack of suitable data. As a result, distribution curves based on professional judgment or derived from very limited data are often employed in the Monte Carlo analysis. These distributions have a high degree of uncertainty, and this uncertainty is propagated through the model with each run. Because of this uncertainty, the final modeling results may not provide defensible risk estimates.

Monte Carlo analysis can add time and cost to conducting a risk assessment, but may provide useful information for RPMs in some cases. Before undertaking a Monte Carlo analysis, be sure that agreements are in place among the risk assessment team, the regulators, and other appropriate parties about the parameters that will be used, the probability distributions to be assigned to each model input parameter, and the methodology. The results of the Monte Carlo analysis should be presented as a supplement to, and not in place of, the deterministic (i.e., nonprobabilistic) HQ-based risk estimate.

Additional information on PRA and Monte Carlo analysis can be found in the *Issue Papers* portion of this web site. EPA policy and principles for PRA and Monte Carlo analysis may be found at http://www.epa.gov/ncea/mcpolicy.htm.

3.7.3 Ecological Significance and Risk Acceptability

Although risks to one or more assessment endpoints may have been identified, these risk estimates alone should not be considered indicative of a need for remediation. Before a final risk characterization and an associated remedial decision are made, the risk estimates should be evaluated with regard to ecological significance and risk acceptability. Ecological significance is related to the likely consequences to the ecosystem that may be incurred from the risks, and acceptability is determined on the basis of those consequences.

3.7.3.1 Factors to Consider when Evaluating Ecological Significance and Risk Acceptability

The evaluation of ecological significance should focus on the expected or observed consequences of the risks to the ecosystem. On the basis of these consequences, the risk assessment team will make a determination of risk acceptability. The determination of ecological significance and risk acceptability should address the following questions:

- *Which assessment endpoints are most at risk?* Although the assessment endpoints were selected to represent ecological entities to be protected, consequences to the ecosystem may vary depending on which assessment endpoints are most at risk. For example, loss of an assessment endpoint that serves as the base of the food chain may result in greater ecosystem disruption than loss of a higher trophic-level endpoint.

- *Where is the greatest impact likely to occur?* Widespread risks (associated with widespread contamination) may cause greater ecosystem disruption than more localized risks (associated with discrete areas of contamination).

- *What is the expected magnitude of the risk?* Risks associated with a greater magnitude in the effect response (e.g., 50% mortality of the wild population) will likely incur greater ecosystem impacts than risks associated with smaller magnitude of effects (e.g., 5% mortality of the wild population).

- *Is the risk associated with a short-term or a long-term effect*? Risks associated with long-term effects may be expected to result in greater ecosystem disruption than risks associated with short-term effects.

- *How are the magnitude and likelihood of occurrence of the impact related?* Risks associated with a high magnitude of response but with a low likelihood of occurrence may exhibit less ecosystem effects than risks associated with a high magnitude and likelihood of adverse effects.

- *What is the potential for recovery of the affected assessment endpoints?* Some endpoints may recover from the effects of COPC exposure more quickly than others may. Thus, some ecosystem impacts may be relatively short-lived.

On the basis of this type of analysis, some of the risk estimates may be deemed to have low ecological significance and thus be considered acceptable.

3.7.3.2 Regulator Concurrence

The evaluation of ecological significance and risk acceptability must be supported with strong, defensible science. Because these evaluations rely heavily on the professional judgment of the risk assessment team, regulator concurrence will be necessary if the evaluations are to support a risk management decision. When presenting the results of the evaluations to the regulators, make sure supporting rationale is provided in a thorough, clear and concise manner. To minimize the potential for disagreements, the evaluations of significance and acceptability should be identified to the regulators early during study design. The risk assessment team should work with the regulators to develop an acceptable set of criteria for determining ecological significance and risk acceptability before data are collected. Decisions regarding ecological significance and risk acceptability should be documented in the WP and SAP.

3.7.4 Uncertainty in the Risk Assessment

Regardless of the risk estimation method employed, some degree of uncertainty and variability will always be associated with the risk characterization, and this uncertainty and variability must be addressed in the BERA. The degree and significance of the uncertainty will directly influence confidence in the BERA results and how the results will be used in the decision-making process.

3.7.4.1 Uncertainty and Variability

Uncertainty represents a lack of knowledge about a poorly characterized phenomenon. In the BERA, uncertainty may result from several factors, including:

- Insufficient information about parameter values and their distributions,
- Simplifying assumptions,
- Insufficient information regarding interactions among the biotic and abiotic components of the site, and
- The likelihood that a particular exposure pathway actually occurs.

Collecting more data can usually reduce uncertainty, although this may not be feasible because of cost or schedule limitations.

Variability represents the heterogeneity in a well-characterized phenomenon. It is inherent in most biological data (e.g., animal weight, ingestion rate), and it can generally be represented by a statistical distribution of values. In contrast to uncertainty, collecting additional data cannot reduce variability.

3.7.4.2 Sources and Consequences of Uncertainty in the BERA

In the BERA, sources of uncertainty may include:

- Conceptual model assumptions, including fate, transport, and exposure pathways,
- Incomplete or insufficient data,
- Natural variability, and
- Analytical error.

Uncertainty in the conceptual model may result in the generation of inappropriate assessment endpoints, risk questions, and risk hypotheses, which in turn directly affect study design. If the data are incomplete or insufficient, it may not be possible to draw appropriate conclusions about the risks posed by site-related COPCs. If the natural variability of the site (i.e., its physical, chemical, and biological components) is not well understood, the results of the BERA may be more reflective of naturally occurring changes in site conditions than in the effects of the COPCs. Uncertainty associated with analytical error may have serious consequences on the interpretation of data and subsequent risk characterization. Adherence to the DQOs and QA/QC procedures should act to minimize uncertainty associated with analytical error.

3.7.4.3 Documenting the Uncertainty

The uncertainty associated with the BERA must be documented in order for the BERA results to support a risk management decision. This documentation should take the form of an uncertainty analysis, which identifies potential sources of uncertainty and the consequences of the uncertainties on the risk characterization. The uncertainty analysis may be qualitative or quantitative, and should:

- Address the expected effect of the uncertainty on the risk characterization,
- Identify any risk that may be over- or under-estimated, and explain why, and
- Identify approaches for reducing uncertainty.

3.7.5 Completing the Risk Characterization

Upon completion of Step 7 *Risk Characterization*, the risk assessment team will have characterized the risks posed by site-related COPCs to the assessment endpoints. For each assessment endpoint, the risk characterization should include a risk estimate, an evaluation of the ecological significance and acceptability of the risk estimate, and an uncertainty analysis. The RPM will now use this information to make a risk management decision and to move the site out of the Tier 2.

3.8 Risk Management, Tier 2 Exit Criteria, and Completion of the Tier 2 BERA

At the conclusion of Step 7 (*Risk Characterization*), the BERA has been completed and site risks characterized. These risks will now be evaluated to support a risk management decision for the site. Depending on the decision made, the site will either exit the ERA process altogether or proceed to Tier 3 *Evaluation of Remedial Alternatives* (Figure 3.1).

3.8.1 Risk Management Considerations

At the conclusion of Tier 2, ecological risks to assessment endpoints were characterized on the basis of ecological significance and risk acceptability. On the basis of this characterization, the RPM must now make a decision on whether the site poses an acceptable or unacceptable level of risk to one or more assessment endpoints.

The primary risk management decision to be made by the RPM will be one of “no action” or “action”. The “no action” decision reflects the BERA findings that the risks posed by the site are acceptable and do not warrant action. Alternately, the “action” decision reflects a characterization of unacceptable risks. If the decision is “action,” then additional risk assessment and risk management decisions will be necessary, and these are undertaken in Tier 3 *Evaluation of Remedial Alternatives*.

3.8.2 Tier 2 Exit Criteria

The CNO Policy for Conducting ERAs identifies two exit criteria (Figure 3.1) to be used in selecting a risk management decision for the site. These criteria are:

- No further evaluation and no remediation from an ecological perspective are warranted because the site does not pose unacceptable risk, or
- The site poses unacceptable ecological risks and additional evaluation in the form of remedy development and evaluation (Tier 3) is appropriate.

If the characterization results support a "no further evaluation and no remediation" decision, the site exits the ERA process. Although this decision stipulates that remediation is not warranted for the site, that finding applies only from an ecological perspective. Consideration of human health risk may indicate a need for remediation. In such a case, additional ERA will be necessary in the form of remedy evaluation, and the site should proceed to Tier 3.

3.8.3 Documentation

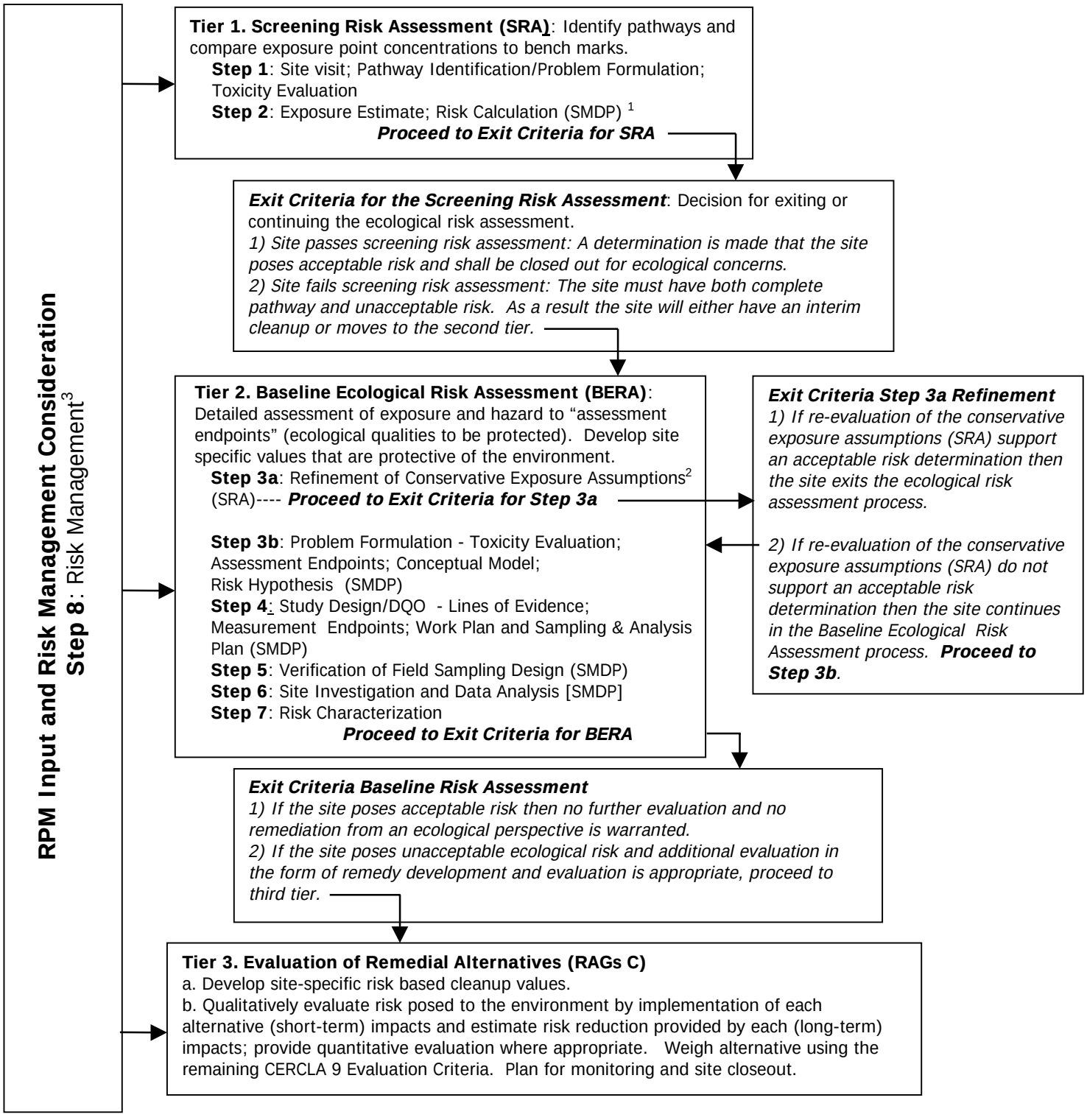
The Tier 2 BERA must be documented regardless of the risk assessment results and subsequent risk management decision (action vs. no action). This documentation should take the form of a technical report consistent with the requirements RAGS Part D (http://www.epa.gov/superfund/programs/risk/ragsd/chapt3.pdf) for preparing a baseline risk assessment report. The BERA report should also incorporate any regulator-specific (i.e., EPA Region-specific) reporting requirements and other report aspects agreed upon between the Navy and the regulators. Regardless of the specific format required, the BERA report should include the following components:

- An introductory overview of the site and discussion of the reason the evaluation was initiated.
- A description of the environmental setting of the site, including physical and ecological characteristics of the site.
- An overview of the operational history or activities that lead to release of the contaminants under evaluation.
- A summary of the Tier 1 SRA and the Tier 2 Step 3a results.
- Identification of the COPCs and a description of the nature and extent of contamination by medium and contaminant type.
- A summary of problem formulation, including the conceptual model and risk questions and hypotheses.
- Identification of the assessment and measurement endpoints.
- A description of the methods employed in the BERA to estimate and characterize risks.
- The results of the exposure and effects assessments.
- The results of risk estimation and characterization.
- The uncertainty analysis.

- A risk summary.
- Technical appendices of modeling results, databases, statistical analyses, and other supporting information as deemed appropriate by the risk assessment team for BERA support, or as requested by the regulators or other appropriate parties.
- Indication of applicable regulator concurrence.

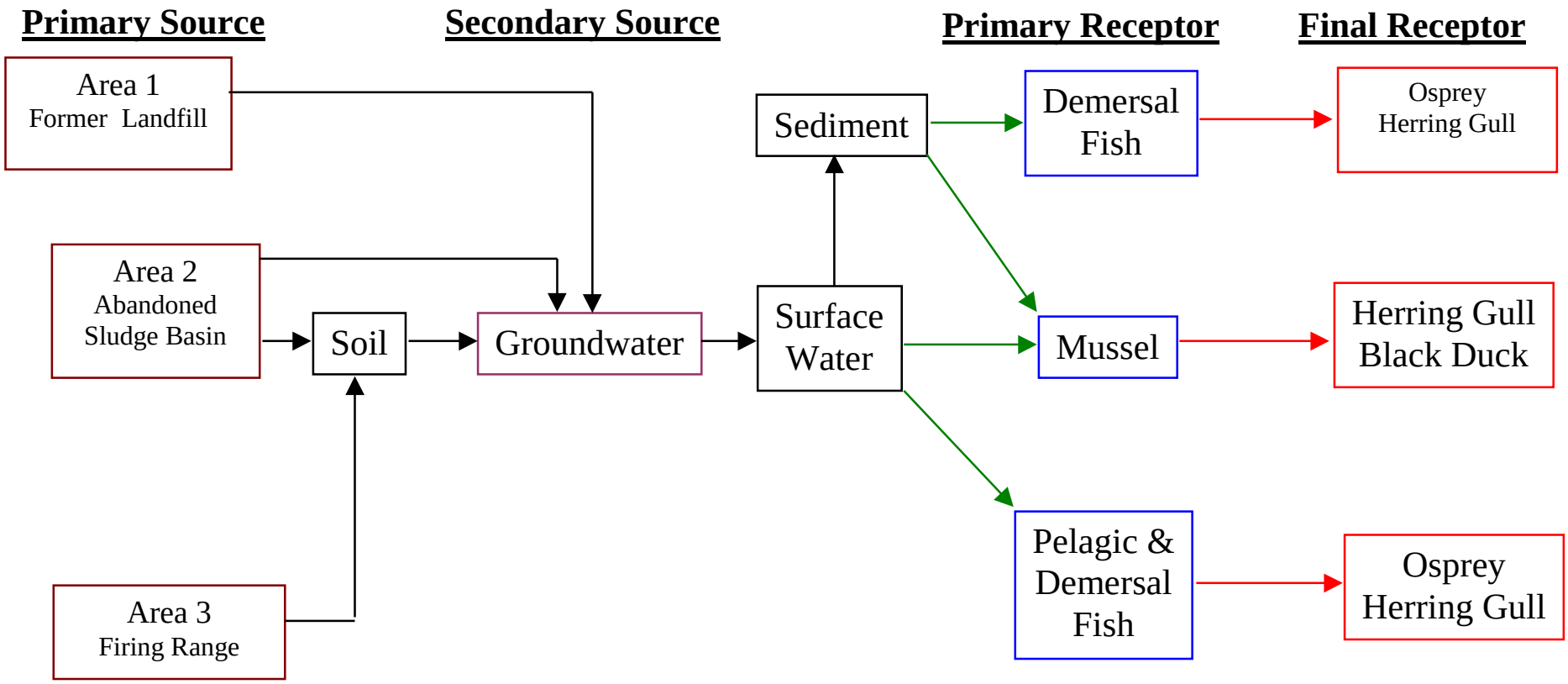
If some detailed information on methods, the Tier 1 SRA, and other aspects of the BERA is available in other documents, such as the WP, SAP, and Tier 1 SRA report, this information should be incorporated by reference. A draft report should be provided to the regulators for review, and a final report should be prepared following receipt and incorporation (as appropriate) of the review comments. Keep in mind that the BERA is part of a RI report. It may be included in the report as a chapter and/or an appendix. Alternately, it may be prepared as a stand-alone volume of a larger RI report.

Figure 3.1 Navy Ecological Risk Assessment Tiered Approach



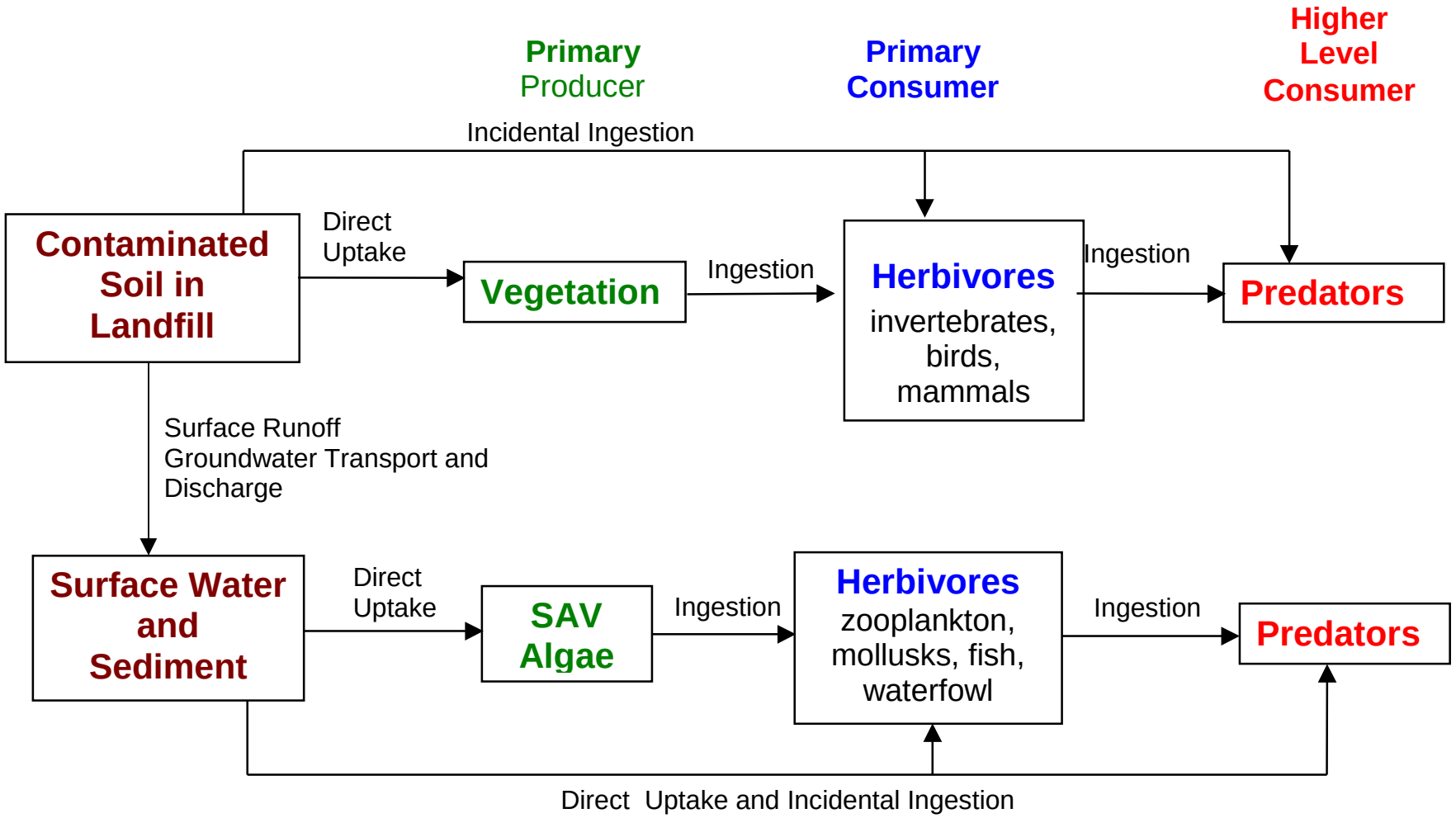
Notes: 1) See EPA's 8 Step ERA Process for requirements for each Scientific Management Decision Point (SMDP).
2) Refinement includes but is not limited to background, bioavailability, detection frequency, etc.
3) Risk Management is incorporated throughout the tiered approach.

Figure 3.2 Example of a Conceptual Site Model for a Nearshore Marine Ecosystem.



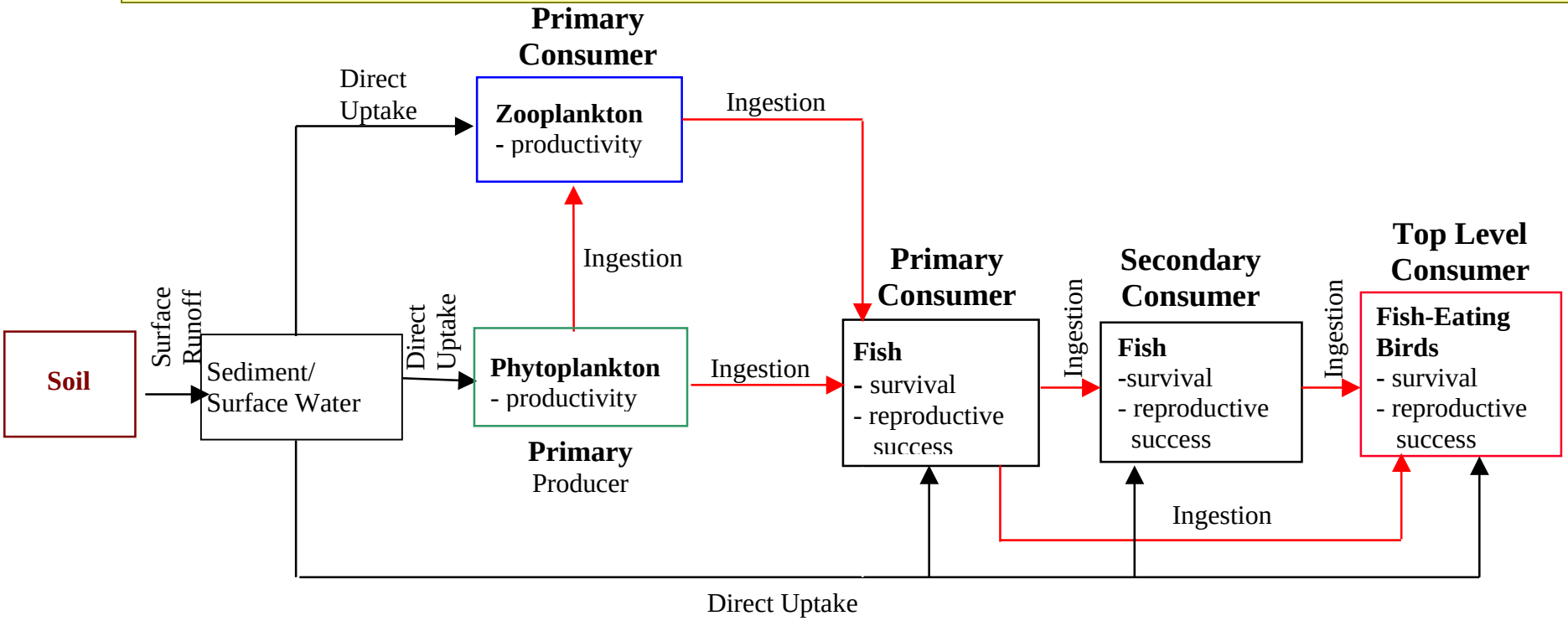
This CSM identifies several contaminant source areas, secondary contaminant sources and media, and exposure pathways to various ecological receptors. The model indicates that contaminants are moving from the primary source areas to surface water and sediment, entering organisms and, through the ingestion of food, reaching black ducks, herring gulls and ospreys. The assessment endpoints (survival and reproduction) are associated with the final receptors. Depending on the toxicological mechanisms of the COPC involved, any combination of the primary and secondary receptors may be selected as assessment endpoints.

Figure 3.3 Example of a Preliminary Conceptual Site Model Developed for the Tier 1 SRA



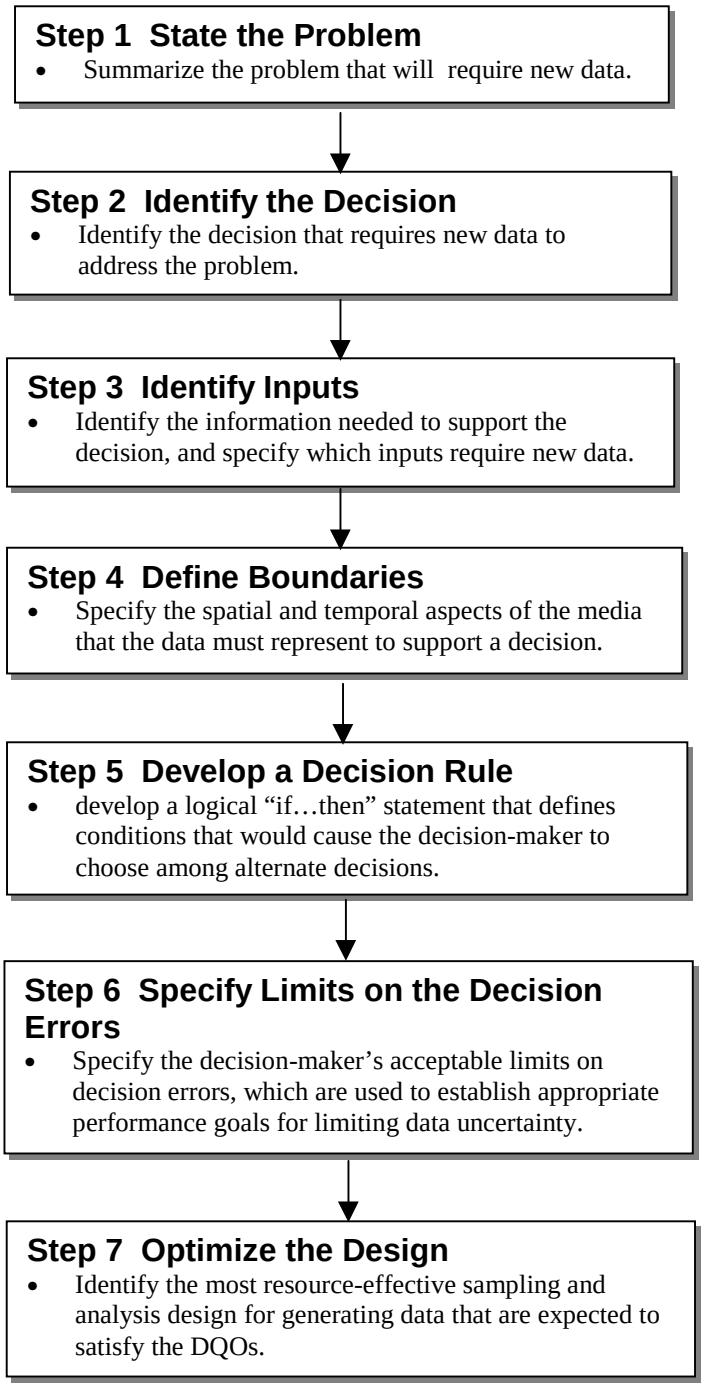
Note that the model identifies assessment endpoints (e.g., primary producers, primary consumers), contaminant sources and media (landfill, soil, sediment, surface water), environmental transport mechanisms (surface runoff, groundwater transport), and exposure routes (direct uptake, ingestion). (SAV = submerged aquatic vegetation)

Figure 3.4 Example of a Tier 2 BERA Conceptual Site Model



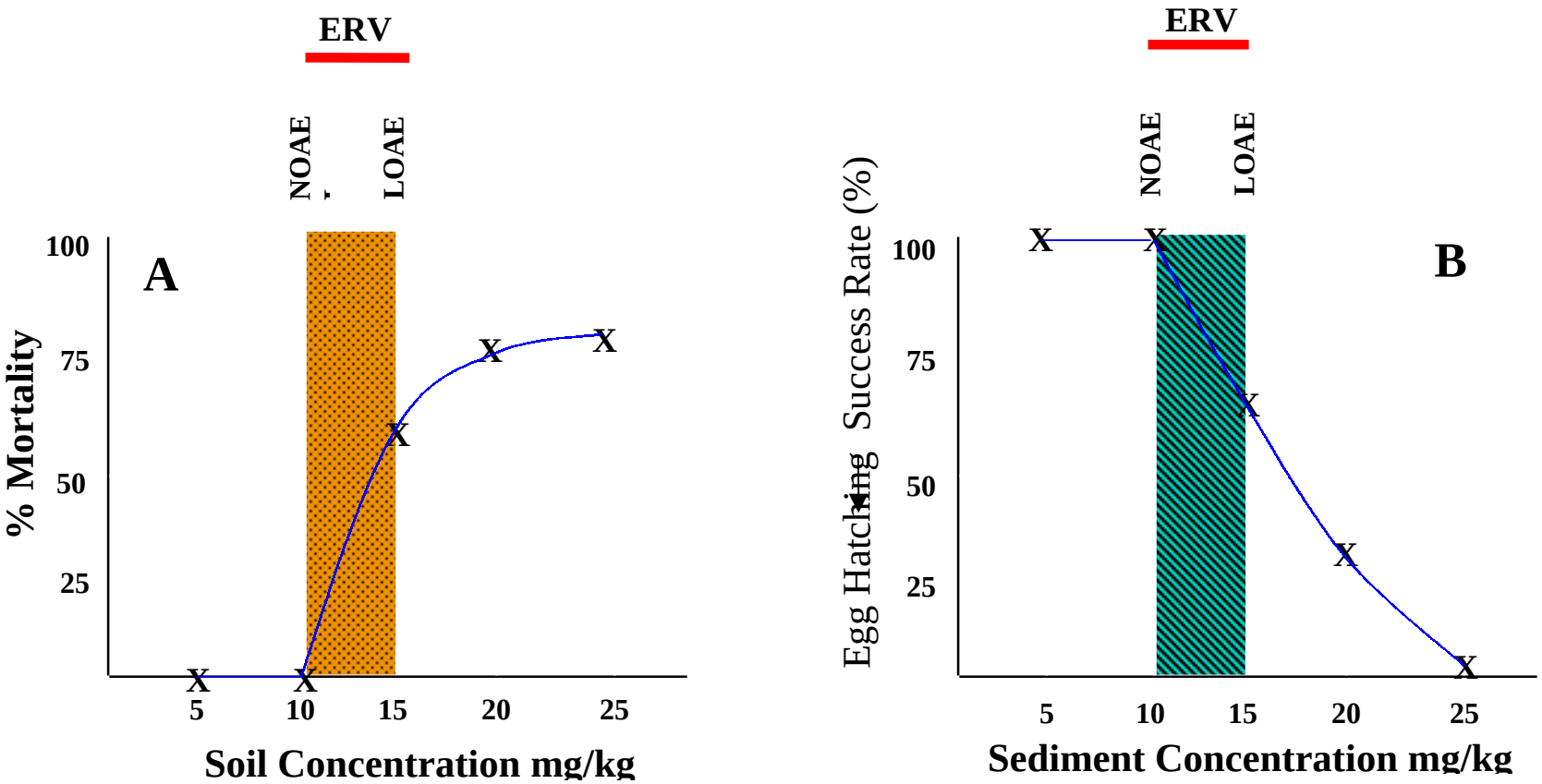
This model identifies the contaminant sources, the fate and transport mechanisms, exposure pathways to ecological receptors (phytoplankton, zooplankton, fish and birds), and the assessment endpoints (productivity of plankton, survival and reproductive success of fish and birds). Note that this model does not identify specific contaminants of concern for each assessment endpoint.

Figure 3.5 The Seven Step Data Quality Objectives Process[1]



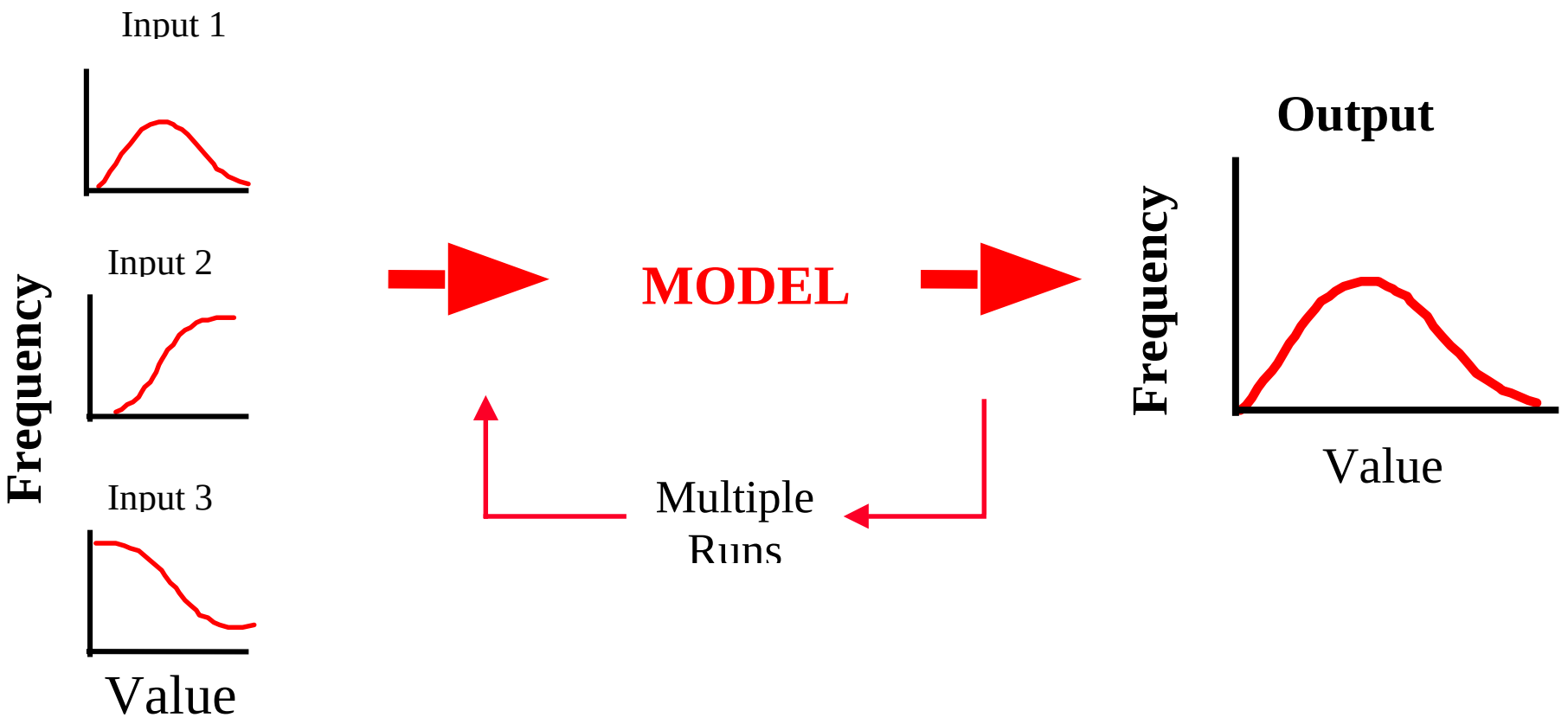
[1] Modified from *Data Quality Objectives Process for Superfund*, 1993, U.S. EPA OSWER Quick Reference Fact Sheet, EPA Publication 9355.9-01 FS, EPA/540/R-93/071, PB94-963205

Figure 3.6 Use of Dose-Response Curves to Identify NOAEL- and LOAEL-Based Ecotoxicity Reference Values



In graph A, earthworm toxicity was evaluated along a soil contamination gradient. The concentration of 10 mg/kg was the highest concentration at which no adverse effects were observed, and this concentration represents the NOAEL. The concentration of 15 mg/kg represents the lowest soil concentration at which adverse effects were observed, and this concentration represents the LOAEL. In graph B, trout egg hatching success was evaluated along a sediment contamination gradient, and the sediment concentrations of 10 mg/kg and 15 mg/kg represent the NOAEL and LOAEL sediment concentrations, respectively. The site-specific ERVs for soil and sediment represent the concentration ranges between the NOAEL and LOAEL values.

Figure 3.7 Monte Carlo Probabilistic Risk Analysis



In a Monte Carlo analysis, data distribution curves are assigned for one or more input variables. These curves may be based on empirical data or on assumptions. The model is then run multiple times (e.g., 1,000 runs), with each run randomly selecting each input parameter value from the distribution curves. Each model iteration output is then plotted to generate a probability distribution curve for the model output, which shows the probability of obtaining a specific output value. In a dose model, the input parameters are the exposure factors (body weight, food ingestion rate, and home range) used in the model, and the output would show the frequency of the modeled receptor's receiving a specific daily contaminant dose.

Table 3.1 Examples of Assessment Endpoints

(Source: modified from the 1998 EPA Guidelines for Ecological Risk Assessment)

Case	Assessment Endpoint
Assessing risks of new chemicals under TSCA	Survival, growth, and reproduction of fish, aquatic invertebrates, and algae.
Review of granular carbofuran based on adverse effects on birds	Individual bird survival.
Modeling future loss of bottomland forest wetlands	Forest community structure and habitat value to wildlife species; species composition of wildlife community
Baird and McGuire Superfund Site	Survival of soil invertebrates; survival and reproduction of song birds.
Waquoit Bay Estuary Watershed Risk Assessment	Estuarine eelgrass habitat abundance and distribution; estuarine fish species diversity and abundance; freshwater pond benthic invertebrate species diversity and abundance.

Table 3.2 Examples of Risk Hypotheses

The first risk hypotheses was developed on the basis of the known chemical and biological behavior of the COPC and similar chemicals, and present what is anticipated to occur in the exposed ecosystem. The second risk hypothesis provides a possible explanation of the relationship between a site-derived contaminant and the observed problem in the local ecosystem. The risk assessors will now design studies to gather the data necessary to prove or disprove the hypotheses. Note that the hypotheses do not identify any study methods, data gaps, or other ERA activities. (Source: modified from the 1998 EPA Guidelines for Ecological Risk Assessment).

Problem/Concern	Hypothesis
Site A is contaminated with chemical A1, which has a K_{OW} of 5 and is chemically similar to chemical B1, which is known to elicit adverse ecological effects. Chemicals with a high K_{OW} tend to bioaccumulate.	Based on the log K_{OW} of A1, the ecotoxicological mechanism of B1, and the food web of the ecosystem present at the site, A1 will bioaccumulate enough in 5 years to levels that will cause developmental problems in fish and wildlife.
The aquatic habitat adjacent to Site B is exhibiting signs of degradation. Large mats of macroalgae are forming in the estuary, increasing turbidity in the water, and a formerly stable brown shrimp fishery appears to have collapsed.	Runoff from the site is carrying chemicals and nutrients into the estuary. The nutrients are increasing algae production which is then eliminating native eelgrass via shading, while the chemicals are directly toxic to the eelgrass. The eelgrass provides required habitat for the brown shrimp, which are disappearing as the eelgrass is eliminated. The algae are also reducing dissolved oxygen to levels below that needed by the shrimp.